Protocol for

Research grant by the Ministry of Health and Welfare in Japan

H11-Health-022 Observational study of unruptured cerebral aneurysms found through screening

Unruptured Cerebral Aneurysm Study of Japan

(UCAS Japan)

CONTENTS

Attached documents

- **Registration forms (FORM H, I~IV)**
- **Reference tables**
- **When you find unruptured cerebral aneurysms (UCAS Japan Patient Registration Manual)**
- **Patient information and informed consent (not included here in this English version)**
- **Imaging criteria (not included here in this English version)**

I. Background

With the advent of less-invasive neuroimaging devices such as magnetic resonance imaging (MRI) and computed tomographic angiography (CTA), it is increasingly common to encounter unruptured cerebral aneurysms in patients. While it is known that subarachnoid hemorrhage from a cerebral aneurysm can often result in a grave prognosis, it is more important to recognize that this disease accounts for 50% of deaths due to stroke in a young population and causes a great loss of important human resources in society. There is a possibility of reducing such events by treating unruptured cerebral aneurysms. Thus, creating a management standard for this disease entity is an important and urgent issue for medical and health policy in Japan. However, the validity and reliability of previous studies of the natural course and treatment of unruptured cerebral aneurysms are questionable because of the number of cases included and their retrospective nature, case selection methods and methods of analysis. Although an international study (ISUIA in 1998) reported results based on a large cohort, the outcome was notably different from those of previous Japanese reports and it is difficult to apply all the information from this study to Japanese medical practice. When deciding how to manage unruptured cerebral aneurysms, including those discovered during screening and with various clinical characteristics, we need ample data to understand the detailed aspects of the aneurysm. To achieve this goal, with the support of the Japan Neurosurgical Society, we planned to create a large-scale database to include both types of unruptured cerebral aneurysms – treated and untreated. We expect this database to become the core of an appropriate guideline for managing unruptured cerebral aneurysms in Japan and elsewhere.

II. Goal

The goal of this study is to clarify the natural course of unruptured cerebral aneurysms. In addition, we will analyze the outcome of the management of this disease in Japan and aim to create a Japanese database of unruptured cerebral aneurysms.

III. Hypothesis

Unruptured cerebral aneurysms 5 mm or larger rupture at an annual rate of 0.5% or more.

IV. Principles

1. This study is a project of the Japan Neurosurgical Society.
2. The management strategy for included cases is decided at the individual institution where the patient is treated.
3. All patients with unruptured cerebral aneurysms observed or treated in the institution are registered during the study period after giving their informed consent.
4. The collaborating institutions are neurosurgical training centers in Japan (Class A and C) and stroke care facilities in Japan.
5. Initially, this study is begun with a research grant from the Ministry of Health and Welfare of Japan. We apply further research grants from other organizations to enable the long-term continuation of the study.
6. Included patients are followed for at least 3 years.
7. After taking measures to protect patients' privacy, we create an efficient Internet registry system for easy and rapid patient registration and prompt data assessment. We create a data center in the University hospital Medical Information Network of Japan (UMIN http://www.umin.ac.jp/english/)
8. Data from this study belongs to the Unruptured Cerebral Aneurysm Study of Japan (UCAS Japan Investigators). The primary report of this study is to be published under the names of these investigators.
9. The coordination office is located in the Department of Neurosurgery at the University of Tokyo
10. We gather information about the management protocol for unruptured cerebral aneurysms in each institution and periodic follow-up information at 3, 12 and 36 months after diagnosis.

V. Clinical Material

Patient criteria

1) All unruptured cerebral aneurysms:
    1. Found during brain doc (screening of healthy population)
    2. Associated with other aneurysm-related subarachnoid hemorrhage
    3. Associated with other disease
    4. Found during study for vague symptoms such as headache or dizziness
    5. Causing cerebral infarction, cranial nerve palsies, etc.
    6. Presenting as unruptured dissecting aneurysms

2) Informed consent obtained from the patient or his/her close relatives
3) Age 20 years or more
4) With no undiagnosed intracranial bleeding source or untreated bleeding pathology other than the unruptured cerebral aneurysm.

Aneurysm criteria

1) Diagnosed with high-speed helical computed tomographic angiography (CTA), magnetic resonance angiography (MRA) with a magnetic specification of 0.5 Tesla or more, or digital subtraction angiography.
2) Diagnosed and measured according to the imaging guideline of this study
3) Size of 3 mm or more
4) Diagnosed by board-certified neurosurgeon, board-certified neurologist or board-certified radiologist
5) Diagnosed with digital subtraction images if the quality of CTA or MRA is not sufficient for accurate diagnosis
6) Accuracy of diagnosis is verified in 10 institutions randomly selected from all collaborating institutions

VI. Ethical criteria

Investigators at each institution obtain the approval of the institutional review board before joining this study. If there is no official institutional review board in the institution, investigators obtain the approval of the hospital committee with a similar role. Each patient is well-informed about the study and gives written consent to participate in this study before registration. The patient information must include a written description of the background, goals, methods, ethical considerations, privacy protection policy**,** consideration and planned actions for possible disadvantages to patients, and contact information at each institution.

VII. Methods

Overview

1) This study is not a controlled trial allocating a specific treatment modality but is a cohort study observing the clinical course of unruptured cerebral aneurysms.
2) By collecting large-scale data of patients with unruptured cerebral aneurysms, we intend to cope with the problem of case selection bias and case volume.

3) To analyze data regarding the rupture rate and management morbidity promptly, we create an Internet data capture system with thorough consideration for and protection of the patient's privacy. If no Internet access is available, data can also be transferred by facsimile to the coordinating office.
4) We aim to register all cases of unruptured cerebral aneurysms encountered at each institution. We prefer the observation and treatment to be decided according to pre-determined criteria.
5) The patients' private information is stored at each institution.

Hospital registration procedures

1) Before a patient is registered, the hospital information should be recorded on FORM H. Data include the date of registration, the name of the hospital, the Japan Neurosurgical Society hospital code, the local investigator's name, the assistant local investigator's name, the mailing address, the telephone and FAX numbers, the model and specification of the CT and MRI machines, the approval of the IRB, and basic criteria for the observation of the unruptured cerebral aneurysms.
2) The patient's information is registered even if the patient refused to follow the hospital protocol for management. But such patients should not exceed 10% of all registered cases.
3) The local investigator should report any change in the policy for managing the unruptured aneurysms to the coordination office.
4) A security ID and password are allocated to each institution for the Internet data entry of patients.
5) A study booklet is sent to each institution. This booklet should be stored in a secure place by the local investigator. This booklet should be passed on to any subsequent investigators.
6) The following items should be stored in the study booklet:
    - The list of patients (new patients are added consecutively)
    - The printed patient privacy form (FORM P: Privacy contact information)
    - The follow-up schedule for each patient
    - A copy of the registration form for each patient at each scheduled and emergency registration time
    - Seals to be attached to the patient's record (notification of entry into UCAS Japan, follow-up registration schedule table (dates)) and the

protocol

Patient registration procedures

1) New patients with unruptured cerebral aneurysms are given information about this study and informed consent is obtained from the patient or his/her close relatives.
2) The investigator enters the online patient registry site using the institutional ID and password allocated by UNIM. The patient's privacy information is then filled out on FORM P to include the name, address, telephone number, and name and address of close relatives.
3) To identify each patient, the patient ID is determined by the hospital code number and the sequential number of the patient. For example, if the patient is the 2219th patient for the institution and the neurosurgery hospital code A-134, the ID for the patient is A-134-002219. **(This plan was later modified so that the UMIN computer automatically assigns a consecutive uniform number (UA******) to each patient in sequence.)**
4) To prevent duplication in the patient database, the registry includes the patient's initials and date of birth. To prevent compromise of this information, the Internet browser should be Explorer 5.1 or Netscape 4.7 or above to make use of 128-bit cryptographic data communication.
5) In the study centers, all new patients with unruptured cerebral aneurysms should have the study explained to them and should be registered after informed consent is obtained.
6) The initial patient registry should be done within 2 weeks of the initial patient interview. If the number of cases registered after 2 weeks exceeds 30% of the total cases of the institution, the steering committee will alert the local investigator.
7) Within 2 weeks of the patient's registration at the initial and follow-up timepoints, an e-mail confirmation is sent to the investigator. If the investigator does not receive the e-mail, there might be some failure in the registration process and the investigator should contact the coordinating office.
8) The initial form (FORM I) is filled out and the data registered for each patient. Information for up to 5 aneurysms per patient can be entered on this form.
9) At the 3-month follow-up, FORM II is completed and the data entered in the registry.

10) At the 12-month follow-up, FORM III is completed and the data entered in the registry.

11) At the 36-month follow-up FORM IV is completed and the data entered in the registry.

(In 2008, a final form (FORM F) was added for patients who were still followed to collect any information available.)

12) An e-mail reminder is automatically sent to investigators 1month before the scheduled follow-up exam of each registered patient.

(This was later modified to 2 weeks before the exam and a reminder e-mail is also sent 2 weeks after a scheduled follow-up if no information is entered at the appropriate time. Modification made in January 2001.)

13) The status change form (FORM C), treatment form (FORM T), and the imaging information (FORM D) are completed and the data entered at the time of scheduled registry if any of these conditions occur between the scheduled follow-ups.

14) The emergency form (FORM E) can be completed at any time during follow-up if a patient leaves the study because of rupture of the aneurysm or death. **(In 2001, we added the patient's transfer, loss to follow-up, or refusal to participate as events to be included on this form.)**

(Please refer to the **Manual of UCAS Japan Patient's Registration** distributed separately.)

VIII. Investigation items

Information collected during the study and at follow-up timepoints are as follows:

◎: Obligatory information

○: Elective information

	Initial registra-tion	3-month follow-up	12-month follow-up	36-month follow-up	Last follow-up in 2008~2009	Event of rupture or death
Neurological status	◎	◎	◎	◎	◎	◎
Imaging information: CTA, MRA or DSA	◎	○	○	○	○	○
Modified Rankin Scale Score	◎	◎	◎	◎	◎	◎

IX. Registration forms

◎: Obligatory information
○: If any data available

	Initial registra-tion	3-month follow-up	12-month follow-up	36-month follow-up	Event of rupture or death	Last follow-up in 2008~2009
Privacy form (**FORM P**)	◎	–	–	–	—	-
Initial form (**FORM I**)	◎	–	–	–	–	–
3-month form (**FORM II**)	–	◎	–	–	–	
12-month form (**FORM III**)	–	–	◎	–	–	
36-month form **(FORM IV)**	–	–	–	◎	-	–
Emergency form (**FORM E**)	–	–	–	–	◎	–
Final form **(FORM F)*4**						○
Change status form **(FORM C)*1**	-	○	○	○	-	○
Treatment form **(FORM T)*2**	-	○	○	○	-	○
Imaging information form **(FORM D)*3**	-	○	○	○	-	○

***1: For any change of status in the patient between the scheduled follow-up timepoints**

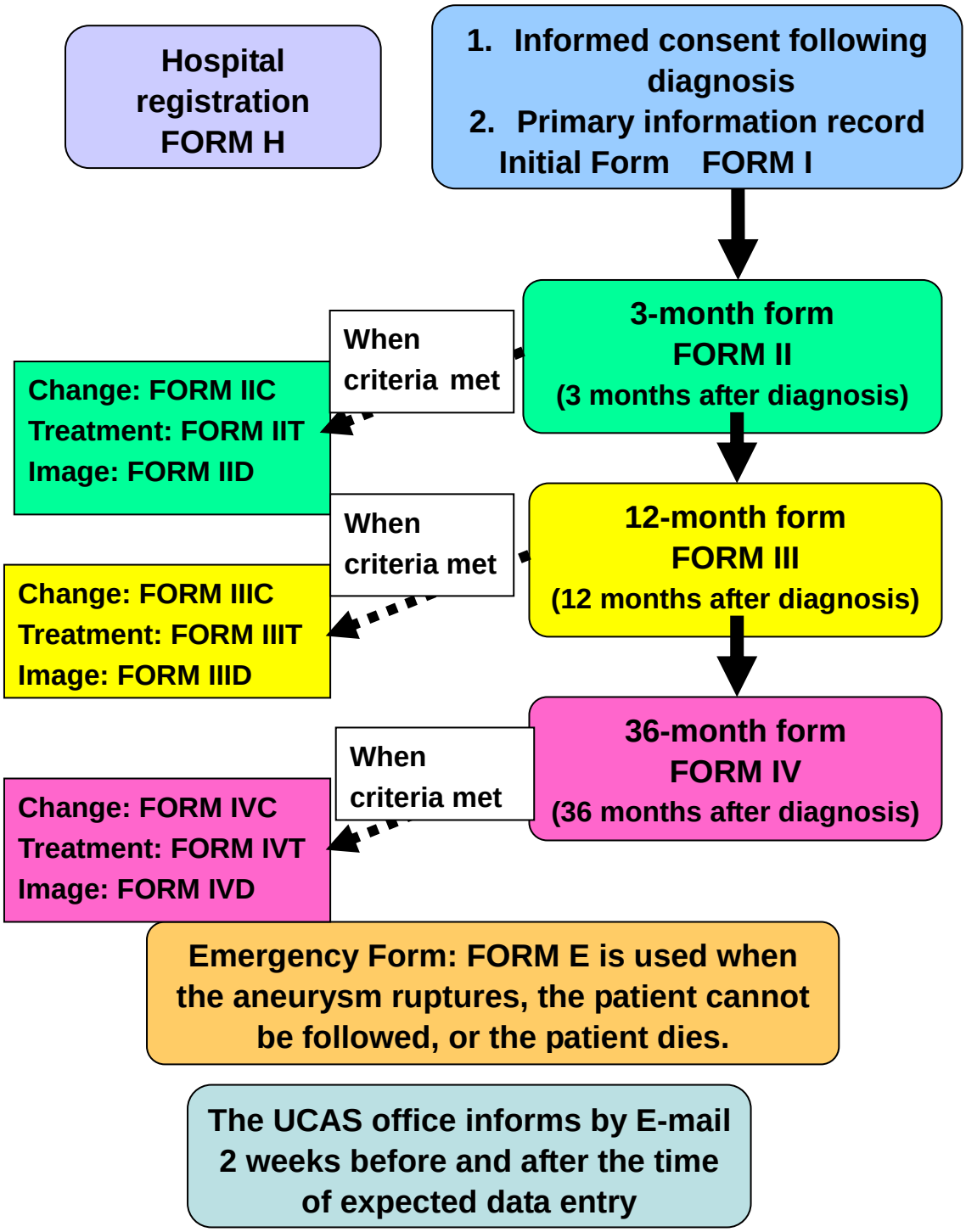
***2: For any treatment done between the scheduled follow-up timepoints**

***3: For any imaging done between the scheduled follow-up timepoints**

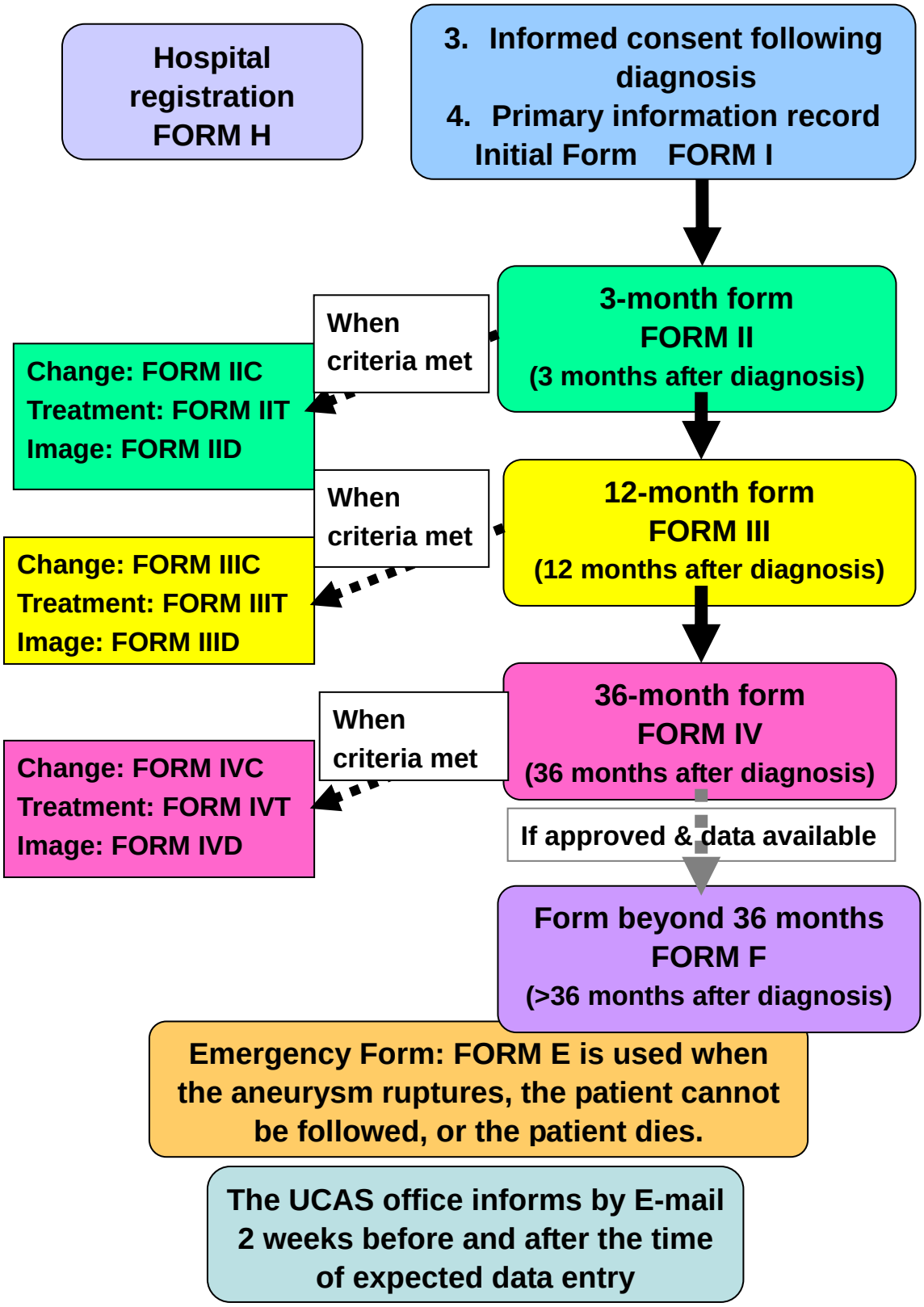
***4: Item added in 2008**

X. Follow-up protocol scheme

Original version



Revised in October 2008



XI. Data monitoring and security protection policy

This committee selects 10 institutions randomly and sends investigators to the institutions to review the registration status annually. The data monitoring committee of this study investigates the following issues:

1. The study is not harming any patient's privacy.
2. All new patients with unruptured cerebral aneurysms who consented to join this study are registered.
3. The study is approved by the local institutional review board.
4. All registered patients agreed to join the study and signed informed consent.
5. Registrations are done correctly at each follow-up timepoint.
6. If any problems in the local registration process are found, a tutorial for the correct method is instituted. Any errors in the registration system or protocol are reported to the steering committee and appropriate action is taken.

XII. End point

Primary end point

Rupture of the involved aneurysm - analyze the risk factors associated with the event

Secondary end point

Mortality rate

Major morbidity rate（worsened modified Rankin scale score of 2 or more）

Minor morbidity rate

Morbidity is evaluated 1 month after treatment and at the time of periodic follow-up.

XIII. Statistical analysis

According to the outcome obtained, the following analysis will be done.

Main research analysis

1. Rupture risk analysis

- Analyze the rupture rate of total cases using the Kaplan-Meier method.
- From the registry of institutions having pre-set criteria for observation (such as observe aneurysms smaller than 5 mm or 10 mm), analyze the aneurysm rupture rate in the group having certain criteria.
- Analyze the rupture rate of all cases, either observed or treated (before

the treatment).

- Analyze the influence of size, shape, location, multiplicity, sex, family history, co-morbidity and habits (especially uncontrolled hypertension or smoking), geographic area or season, and differences in stress at the time of rupture. Perform multivariate Cox Hazard Regression Analysis using such variables. Define the factors predicting rupture.

The following data will be collected for reference:

2. Assess the treatment morbidity

Analyze the risk factors associated with treatment morbidity (decline of the modified Rankin scale score of 2 or more) and mortality, such as the method of treatment, size, location, shape, and institutional volume of cases.

XIV. Numerical goal of patient registry

This registry aims to create a data bank of the outcome of unruptured cerebral aneurysms in Japan. Therefore, we will collect as many cases as possible during the study period. We sent a questionnaire to all neurosurgical institutions in Japan (about 1,143) and 271institutions (22%) replied with a total of 5,707 cases of unruptured cerebral aneurysms. Therefore, we expect at least 3,000~5,000 new cases will be registered each year.

XV. Study period

We will register new cases for 3 years and follow all cases for 3 years. Registration is to begin January 1, 2001.

(This plan was modified in October of 2008 to have the final follow-up in 2008~2009 if any data were available.)

XVI. Organization of this study

Revised in 2010

Steering Committee (*WC:* Writing committee members)

T Kirino (Study Chair, *WC*), K Hashi (Study Co-chair, *WC*), **A Morita (Principal coordinator, Writing committee chair)**, **I Date**, S Fukuhara (*WC*), T Fukui, **N Aoki (*WC*),** N Hashimoto (*WC*), **K Houkin,** T Kawase, T Kiuchi, **T Nakayama (*WC*),** Y Ohashi, T Ohmoto, I Saito, **N Saito, M Sakai (*WC*),** T Sakurai, **Y Shiokawa, A Teramoto (*WC*), T Tominaga, S Tominari (*WC*),** T Yamaki, T Yoshimoto (*WC*)

Investigators

H Arai, Y Iwasaki, H Kajikawa, Y Katayama, T Kanno, N Kodama, K Kurisu, C Ochiai, A Ogawa, K Saito, N Sakai, T Sasaki(Fukuoka), T Sasaki(Sapporo), H Sano, H Segawa, A Takahashi, W Taki, **S Nagao,** T Nakagawa, I Nagata, M Negoro, S Fujiwara, T Hori, T Matsushima, **M Matsutani,** S Miyamoto, A Yamaura, N Yasui, T Yasui, **J Yoshida,** T Yoshimine, K Watanabe, **E Watanabe**

Statistical Committee

N Aoki, S Fukuhara, T Fukui, **T Nakayama,** Y Ohashi, **M Sakai,** T Sakurai

Data and Safety Monitoring Committee

K Takakura, Y Fukuuchi, T Fukui, T Sakurai

Image Confirmation Committee

T Maehara, S Tanabe, **S Aoki**

Coordination Center

A Morita (Principal coordinator), T Kiuchi, **N Sato, M Uchida, M Yamamoto**

XVII. Time table of this study

The list of committees before this study starts and planned initiation of the study.

1. Aug 27, 1999: Acting board pre-meeting The 1st pre-study protocol review meeting
2. Oct 26, 1999:Conduction of this study was approved by the Japan Neurosurgical Society Board Member committee.
3. Dec 1999:Approval of contents of questionnaire by acting board
4. Dec. 1999: Sent Questionnaires regarding the care of unruptured cerebral aneurysms in each institution
5. Feb 21, 2000: UCAS Japan Protocol and Internet registry review meeting, (members: Takaaki Kirino, Kazuo Hashi, Yasuo Ohashi, Takahiro Kiuchi, Akio Morita, Noriaki Yamaki)
6. March, 2000: Protocol review meeting (members: Kirino, Fukuhara, Ohashi, Morita)
7. April, 2000: Questionnaires summarized (coordinating office)
8. April 27, 2000: Presentation on the protocol of UCAS Japan in the 25th Japan Stroke Society Annual meeting(By K Hashi)
9. May 20, 2000: Presentation of the summary of questionnaire regarding care of the unruptured cerebral aneurysms in Japan, at the 20th Japanese Congress of Neurological Surgeon (by T Kirino) and 1st UCAS Japan Acting Board Meeting
10. July 2000: Homepage of UCAS Japan opened and UCAS Japan Introductory Papers distributed to all Japanese Neurosurgical Training Centers
11. Sept 2, 2000: The second Acting Board Meeting during Mt Fuji Workshop
12. Oct .2000: Internet registry built
13. Sept. ~ Oct 2000: Test of internet registry by entering 30 cases from institutions related with investigators
14. Oct 25, 2000: 1st Local Investigator Meeting at the Japan Neurosurgical Society Annual Meeting at Fukuoka.
15. Jan. 2001: Internet registry will be started.

Attached documents

Registration forms for UCAS Japan

Hospital registration form（FORM H）

Register this information before starting case entry

- Registration Date：　　／　　／
  （Example;2001／01／15）
- Institution name：
- Japan Neurosurgical Society Institutional code
  ☐A-　☐ C-　☐ N-
- UCAS J local investigator:
- E-mail address：
- Sub-investigator：
- E-mail:
- MRA machine model name：　　：　　tesla
- CTA machine model name：
- Annual case volume:

Year	Aneurysm surgery including ruptured/unrup-tured	Total neurosurgical surgical volume	Endovascular procedures for aneurysms (ruptured/unrup-tured)	Total endovascular procedures
1999				
2000				

- Basic management criteria of the institution（check one for the indication of observation and timing）

Observation criteria

☐ All unruptured intracranial aneurysms
☐ Aneurysms less than 10 mm
☐ Aneurysms less than 5 mm
☐ Aneurysms less than 3 mm
☐ None of above

Timing of treatment if indicated

☐ Within 1 month
☐ During 1~3 months
☐ After 3 months
☐ None of above

Privacy information form (FORM P)

This data should be filled for all new patients, printed and stored at each institution.

This data is not for online registration

- Date of diagnosis: ／ ／
- Patient's hospital identification number (ID):
- Name:
- Date of birth ／ ／
- Age:
- Current address:
- TEL:
- Name of next to kin:
- Contact address:
- Sex: ☐ Male ☐ Female
- Location of aneurysms (may check multiple boxes): ☐ R ☐ L ☐ Midline

☐ IC-P Com ☐ IC-A Choroidal ☐ IC Bifurcation

☐ IC-Paraclinoid ☐ So-called IC dorsal ☐ IC cavernous (extradural)

☐ MCA ☐ A Com ☐ A1 ☐ A2 ☐ Other supratentorial

☐ VA-PICA ☐ VA union (VB junction) ☐ VA dissection

☐ BA-Top ☐ BA-SCA ☐ Other infratentorial

Initial registration（FORM I）DAY 0

Register within 2weeks after obtaining informed consent

- Informed consent: ☐ Yes ☐ No
- **Hospital code: ☐ A- ☐ C- ☐ N-**
- Patient ID:
- Sex: ☐ Male ☐ Female
- Patient's name (initials only):
- Age:
- Date of birth: ／ ／
- Date of initial consult*: ／ ／
- Date of diagnosis confirmation: ／ ／

*: Date of initial consult regarding the medical issue, which resulted in the detection of an unruptured intracranial aneurysm (UIA)

- Diagnostic measure confirmed UIA: ☐ Angiography (including digital subtraction angiography) ☐ MRA ☐ 3D CTA

- Reason for medical consult and diagnosis:

☐ Brain dock
☐ Screening of central nervous system disease during check-up of general health
☐ Evaluation of vague symptoms such as headache, vertigo, or dizziness
☐ Symptoms probably related to aneurysm（such as cranial nerve palsies, embolic events, etc.）
☐ Evaluation of subarachnoid hemorrhage (SAH) (UIAs associated with other aneurysm-caused SAH)
☐ Other

- Past medical/social history（May check multiple boxes）:

☐ SAH ☐ Hypertension with good medical control ☐ Poorly controlled hypertension ☐ Smoking (current) ☐ Diabetes mellitus ☐ Hyperlipidemia ☐ Ischemic strokes ☐ Polycystic kidney disease**(added Oct 2001)** ☐ None, or other

- Family history of SAH（May check multiple boxes）:

☐ Parents, or children（☐ Father、☐ Mother、☐ Son、☐ Daughter）
☐ Siblings（☐ Brother、☐ Sister）
☐ Other relatives（☐ Male、☐Female）

☐ None, or unknown

- Neurological Findings:

1）Neurological deficits（May check multiple boxes）

☐ None ☐ Motor palsy ☐ Sensory disturbance
☐ Speech disturbance ☐ Cranial nerve deficits ☐ Disequilibrium
☐ Other

2）Modified Rankin scale: [ ]（Reference table 1）

- Number of UIAs: [ ]

(Register up to 5 aneurysms per patient in cases with multiple aneurysms.)

（Repeat following column according to the number of UIAs）

- UIA index:○1○2○3○4○5（Register from larger aneurysm）
- Location of aneurysms：☐ R ☐ L ☐ Midline

☐ IC-P Com ☐ IC-A Choroidal ☐ IC Bifurcation
☐ IC-Paraclinoid ☐ So-called IC dorsal ☐ IC cavernous (extradural)
☐ MCA ☐ A Com ☐ A1 ☐ A2 ☐ Other supratentorial
☐ VA-PICA ☐ VA union (VB junction) ☐ VA dissection
☐ BA-Top ☐ BA-SCA ☐ Other infratentorial

- Maximum diameter of the aneurysm：[ ]mm (register by mm unit)
- Shape:

☐ Saccular ☐ Fusiform

- Calcification:

☐ Yes ☐ No

- Thrombosis:

☐ Yes ☐ No

- Daughter sac:

☐ Yes（>1mm）
☐ Yes（<1mm）
☐ No

- Initial management plan:

☐ Observation without special restriction
☐ Observation with careful follow-up and medical consult
☐ Craniotomy
☐ Endovascular intervention
☐ Undetermined

- Follow basic management protocol registered on FORM H

☐ Follow basic plan ☐ No

- Reason for choosing observation（record one main reason）

☐ Refusal of the treatment by the patient or family ☐ Patient's age
☐ Health status ☐ Risk of surgery
☐ Size of UIA ☐ Location of UIA
☐ Protocol ☐ Other

3-month registration (FORM II)

Register the patient's status 3 months after the initial consult (Day 0 of Form I)

- **UA number:*UA**
- Date of observation: ／ ／
- **Hospital code: ☐ A- ☐ C- ☐ N-**
- **Name of the hospital:**
- **Patient hospital ID:**
- **Patient's name (initials only):**

Blue information will be automatically indicated when registering at the online registration page.

*** UA number is the UCAS Japan patient identification number, which is assigned to each patient automatically as soon as the initial registration is recorded.**

- Change of patient's status during the interim

(such as rupture, neurological change, death, etc.):

☐ Yes ☐ No (Register FORM II C if Yes)

- Date of change: / /

- Any treatment during the interim:

☐ Yes ☐ No (Register FORM II T if Yes)

- Date of Treatment: / /

- Any imaging during the interim:

☐ Yes ☐ No (Register FORM II D if Yes)

- Date of Imaging: / /

- Neurological Findings:

1) Neurological deficits (May check multiple boxes)

☐ None ☐ Motor palsy ☐ Sensory disturbance
☐ Speech disturbance ☐ Cranial nerve deficits ☐ Disequilibrium
☐ Other

2) Disturbed consciousness ☐ Yes ☐ No

If yes, register Glasgow Coma Scale (reference table 2):

Best Eye Response:	Best Verbal response:	Best Motor Response:

3) Modified Rankin scale: ☐ (Reference table 1)

Change record 3 months (FORM IIC)

Register if any change of patient's clinical status or aneurysm rupture during the interim

- **UA number**: UA
- **Hospital code**: ☐ A- ☐ C- ☐ N-
- **Name of the hospital:**
- **Patient hospital ID**:
- **Patient's name (initials only):**
- **Date of change**: ／ ／
- **Change type**

☐ Rupture of aneurysm（☐ Recorded aneurysm: UIA index ○1○2○3○4○5、
☐ new aneurysm ☐ unknown）
☐ Intracerebral hemorrhage（Relation with aneurysm: ☐ Yes ☐ No ☐ Unknown）
☐ Cerebral infarction（Relation with aneurysm: ☐ Yes ☐ No ☐ Unknown）
☐ Cranial nerve palsy
☐ Death unrelated to UIAs

In case of rupture, register the following information

- Status of stress when rupture occurred

Physical: ☐ Heavy duty labor ☐ During sleep ☐ Other
Emotional: ☐ Stressed ☐ During sleep ☐ Other

- Level of consciousness at the Emergency room

Glasgow Coma Scale〔Reference table 2〕:
Best eye response: Best verbal response: Best motor response:
WFNS grade〔Reference table 3〕:

- Diagnosis of SAH

☐ CT scan ☐ Cerebrospinal fluid ☐ Autopsy ☐ None, other

- Grade of SAH（CT classification）

Fischer's classification〔Reference table 3〕
☐ I ☐ II ☐ III ☐ IV

- Last known modified Rankin scale: （Reference table 1）
- End of the study?: ☐ End ☐ Continue
- Reason for end: ☐ Aneurysm rupture ☐ Death ☐ Other

○ **Return to 3-month registration form**

Treatment record 3 months（FORM IIT）

Register if any treatment during the interim

- **UA number*:** UA
- **Hospital code:** ☐ A- ☐ C- ☐ N-
- **Name of the hospital:**
- **Patient hospital ID:**
- **Patient's name (initials only):**

- Number of aneurysms treated:

- UIA index treated: ○1○2○3○4○5
- Method of treatment:

  ☐ Craniotomy (Clipping, etc.)
  ☐ Endovascular treatment
  ☐ Both (combined)

- Reason for treatment（Choose one reason which influenced the decision most）

☐ Desire of the patient or family
☐ Age
☐ Related with SAH
High risk of rupture（☐ Size ☐ Shape ☐ Location）
☐ Change of aneurysm (such as enlargement, etc.)
☐ Appearance of symptoms（such as cranial nerve palsy, etc.）
☐ Rupture
☐ Other

- Date of treatment: ☐☐/☐☐/☐☐
- Imaging after the treatment:

☐ Yes ☐ No

If Yes:

- Type of imaging: ☐ Angiography ☐ MRA, ☐ 3D CTA
- Effect of treatment: ☐ Complete occlusion ☐ Incomplete occlusion

（Incomplete occlusion; Residual neck+ after clipping or obliteration rate <90% after coiling）

Repeat 2~5 times if multiple aneurysms were treated（up to 5 times）

- Outcome/ Neurological status 1 month after the treatment

1) Neurological deficits (May check multiple boxes)

☐ None ☐ Motor palsy ☐ Sensory disturbance
☐ Speech disturbance ☐ Cranial nerve deficits ☐ Disequilibrium
☐ Other

2) *Rankin scale:* ☐ (Reference table 1)

3) *Relation between neurological deficits and treatment* (if there is new neurological deficit)

☐ Yes ☐ No ☐ Unknown

- If yes, list intra- or peri-operative events most likely inducing the deficits:

☐ Perforator injury ☐ Parent artery occlusion ☐Venous injury
☐ Cerebral retraction, temporary occlusion of the parent artery
☐ Intraoperative rupture ☐ Other surgical insults
☐ General complication during surgery ☐ Complication after surgery

4) Other peri-operative complications ☐ Yes ☐ No

- If Yes, check below:

☐ Hydrocephalus ☐ Intracerebral hemorrhage ☐Seizure
☐ Wound infection ☐ Meningitis ☐ Olfactory disturbance
☐ Vision change ☐ Subdural hygroma, hematoma
☐ Facial frontal branch palsy ☐ Pneumonia
☐ Deep vein thrombosis of lower extremities
☐ Gastrointestinal bleeding ☐ Drug allergy ☐ Other

○Return to 3-month registration form

Image follow-up record 3-month (FORM IID)

Register if any imaging was obtained during the interim

- Date of imaging: ☐☐/☐☐/☐☐☐☐
- **UA number: UA** ☐☐☐☐☐☐
- **Hospital code: ☐ A- ☐ C- ☐ N-** ☐☐☐
- **Name of the hospital:** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
- **Patient hospital ID:** ☐☐☐☐☐☐☐☐
- **Patient's name (initials only):**
- Type of imaging: ☐ MRA ☐ CTA ☐ Angiography ☐ CT ☐ MRI
- Findings:

☐ Cerebral infarction ☐ Hydrocephalus ☐ Brain atrophy ☐ New aneurysm
☐ Intracerebral hemorrhage ☐ Other ☐ None

- Findings on aneurysms: ☐ Change ☐ No change
- If any change, record the following:

UIA index with any change: ○1 ○2 ○3 ○4 ○5

- Size:

☐ Same ☐ Enlargement（☐☐mm、☐☐%） ☐ Shrinkage（☐☐mm、☐☐%）
☐ Complete obliteration from treatment
☐ Incomplete obliteration from treatment

- Shape:

☐ Unchanged ☐ Changed

（Repeat if any changes in multiple aneurysms）

- Is the imaging obtained after treatment: ☐ Post treatment ☐ No

Register below if this is post-treatment

- Any imaging change by the treatment: ☐ Yes ☐ No
  - ➢ If yes, record below:

☐ Cerebral infarction ☐ Brain contusion ☐Subdural hygroma ☐ Subdural hematoma
☐ Hydrocephalus ☐ Other

○**Return to 3-month registration form**

12-month registration (FORM III)

Register the patient's status 12 months after the initial consult (Day 0 of Form I)

- **UA number*:UA**
- Date of observation: / /
- **Hospital code: ☐ A- ☐ C- ☐ N-**
- **Name of the hospital:**
- **Patient hospital ID:**
- **Patient's name (initials only):**

Blue information will be automatically indicated when registering at the online registration page.

*** UA number is the UCAS Japan patient identification number, which is assigned to each patient automatically as soon as the initial registration is recorded.**

- Change of patient's status during the interim

(Such as rupture, neurological change, death, etc.):

☐ Yes ☐ No (Register FORM IIC if Yes)

- Date of change: / /

- Any treatment during the interim:

☐ Yes ☐ No (Register FORM IIT if Yes)

- Date of Treatment: / /

- Any imaging during the interim:

☐ Yes ☐ No (Register FORM IID if Yes)

- Date of Imaging: / /

- Neurological Findings:

1) Neurological deficits (May check multiple boxes:)

☐ None ☐ Motor palsy ☐ Sensory disturbance
☐ Speech disturbance ☐ Cranial nerve deficits ☐ Disequilibrium
☐ Other

2) Disturbed consciousness ☐ Yes ☐ No

If yes, register Glasgow Coma Scale (reference table 2):

Best Eye Response:	Best Verbal response:	Best Motor Response:

3) Modified Rankin scale: ☐ (Reference table 1)

Change record 12-month (FORM IIIC)

Register if any change in patient's clinical status or aneurysm rupture during the interim

- **UA number**: UA
- **Hospital code**: ☐ A- ☐ C- ☐ N-
- **Name of the hospital:**
- **Patient hospital ID**:
- **Patient's name (initials only)**:
- **Date of change**: ／ ／
- **Change type**

☐ Rupture of aneurysm（☐ Recorded aneurysm: UIA index ○1○2○3○4○5)、
☐ New aneurysm ☐ Unknown）
☐ Intracerebral hemorrhage（Relation to aneurysm: ☐ Yes ☐ No ☐ Unknown）
☐ Cerebral infarction（Relation to aneurysm: ☐ Yes ☐ No ☐ Unknown）
☐ Cranial nerve palsy
☐ Death unrelated to UIAs

In case of rupture, register the following information:

- Status of stress when rupture occurred

Physical: ☐ Heavy-duty labor ☐ During sleep ☐ Other
Emotional: ☐ Stressed ☐ During sleep ☐ Other

- Level of consciousness at the Emergency room

Glasgow Coma Scale〔Reference table 2〕:
Best eye response: Best verbal response: Best motor response:
WFNS grade〔Reference table 3〕:

- Diagnosis of SAH

☐ CT scan ☐ Cerebrospinal fluid ☐ Autopsy ☐ None, other

- Grade of SAH（CT classification）

Fischer's classification〔Reference table 4〕
☐ I ☐ II ☐ III ☐ IV

- Last known modified Rankin scale: （Reference table 1）
- End of the study?: ☐ End ☐ Continue
- Reason for End: ☐ Aneurysm rupture ☐ Death ☐ Other

○ **Return to 12-month registration form**

Treatment record 12-month（FORM IIIT）

Register if any treatment during the interim

- **UA number*:** UA
- **Hospital code:** ☐ A- ☐ C- ☐ N-
- **Name of the hospital:**
- **Patient hospital ID:**
- **Patient's name (initials only):**

- Number of aneurysms treated:

- UIA index treated: ○1○2○3○4○5
- Method of treatment:

  ☐ Craniotomy (Clipping, etc.)
  ☐ Endovascular treatment
  ☐ Both (combined)

- Reason for treatment（Choose one reason which influenced the decision most）

☐ Desire of the patient or family
☐ Age
☐ Related to SAH
High risk of rupture（☐ Size ☐ Shape ☐ Location）
☐ Change of aneurysm (such as enlargement, etc.)
☐ Appearance of symptoms（such as cranial nerve palsy, etc.）
☐ Rupture
☐ Other

- Date of treatment: ☐☐☐☐/☐☐/
- Imaging after the treatment:

☐ Yes ☐ No

If Yes:

- Type of imaging: ☐ Angiography ☐ MRA, ☐ 3D CTA
- Effect of treatment: ☐ Complete occlusion ☐ Incomplete occlusion

（Incomplete occlusion: Residual neck after clipping or obliteration rate <90% after coiling）

Repeat 2~5 times if multiple aneurysms were treated（up to 5 times）

- Outcome/Neurological status 1 month after the treatment

1）Neurological deficits（May check multiple boxes）

☐ None ☐ Motor palsy ☐ Sensory disturbance
☐ Speech disturbance ☐ Cranial nerve deficits ☐ Disequilibrium
☐ Other

2) *Rankin scale:* ☐ (Reference table 1)

3) *Relation between neurological deficits and treatment* (if there is new neurological deficit)

☐ Yes ☐ No ☐ Unknown

- If Yes, list intra- or peri-operative events most likely to induce the deficits:

☐ Perforator injury ☐ Parent artery occlusion ☐Venous injury
☐ Cerebral retraction, temporary occlusion of the parent artery
☐ Intraoperative rupture ☐ Other surgical insults
☐ General complication during surgery ☐ Complication after surgery

4) Other peri-operative complications: ☐ Yes ☐ No

- If Yes, check below:

☐ Hydrocephalus ☐ Intracerebral hemorrhage ☐Seizure
☐ Wound infection ☐ Meningitis ☐ Olfactory disturbance
☐ Vision change ☐ Subdural hygroma, hematoma
☐ Facial frontal branch palsy ☐ Pneumonia
☐ Deep vein thrombosis of lower extremities
☐ Gastrointestinal bleeding ☐ Drug allergy ☐ Other

○Return to 12-month registration form

Image follow-up record 12-month (FORM IIID)

Register if any imaging was obtained during the interim

- Date of imaging: ／ ／
- **UA number: UA**
- **Hospital code: ☐ A- ☐ C- ☐ N-**
- **Name of the hospital:**
- **Patient hospital ID:**
- **Patient's name (initials only):**
- Type of imaging: ☐ MRA ☐ CTA ☐ Angiography ☐ CT ☐ MRI
- Findings:

☐ Cerebral infarction ☐ Hydrocephalus ☐ Brain atrophy ☐ New aneurysm
☐ Intracerebral hemorrhage ☐ Other ☐ None

- Findings on aneurysms: ☐ Change ☐ No change
- If any change, record the following:

UIA index with any change: ○1 ○2 ○3 ○4 ○5

- Size:

☐ Same ☐ Enlargement（ mm、 %） ☐ Shrinkage（ mm、 %）
☐ Complete obliteration by the treatment
☐ Incomplete obliteration by the treatment

- Shape:

☐ Unchanged ☐ Changed

（Repeat if any changes in multiple aneurysms）

- Is the imaging obtained after treatment?: ☐ Post treatment ☐ No

Register below if this is post-treatment

- Any imaging change by the treatment: ☐ Yes ☐ No
  - ➢ If yes, record below:

☐ Cerebral infarction ☐ Brain contusion ☐Subdural hygroma ☐ Subdural hematoma
☐ Hydrocephalus ☐ Other

○ **Return to 12-month registration form**

36-month registration (FORM IV)

Register the patient's status 36 months after the initial consult (Day 0 of Form I)

- **UA number*: UA**
- Date of observation: ／ ／
- **Hospital code: ☐ A- ☐ C- ☐ N-**
- **Name of the hospital:**
- **Patient hospital ID:**
- **Patient's name (initials only):**

Blue information will be automatically indicated when registering at the online registration page.

*** UA number is the UCAS Japan patient identification number, which is assigned to each patient automatically as soon as the initial registration is recorded.**

- Change of patient's status during the interim

(such as rupture, neurological change, death, etc.):

☐ Yes ☐ No (If yes, register FORM IIC)

  - Date of change: / /

- Any treatment during the interim:

☐ Yes ☐ No (If yes, register FORM IIT)

  - Date of Treatment: / /

- Any Imaging during the interim:

☐ Yes ☐ No (If yes, register FORM IID)

  - Date of Imaging: / /

- Neurological Findings:

1) Neurological deficits (May check multiple boxes)

☐ None ☐ Motor palsy ☐ Sensory disturbance
☐ Speech disturbance ☐ Cranial nerve deficits ☐ Disequilibrium
☐ Other

2) Disturbed consciousness ☐ Yes ☐ No

If yes, register Glasgow Coma Scale (reference table 2):

Best Eye Response:	Best Verbal response:	Best Motor Response:

3) Modified Rankin scale: ☐ (Reference table 1)

Change record 36 months (FORM IVC)

Register if any change of patient's clinical status or aneurysm rupture during the interim

- **UA number**: UA
- **Hospital code**: ☐ A- ☐ C- ☐ N-
- **Name of the hospital:**
- **Patient hospital ID**:
- **Patient's name (initials only):**
- **Date of change**: ／ ／
- **Change type**

☐ Rupture of aneurysm（☐ Recorded aneurysm: UIA index ○1○2○3○4○5、
☐ New aneurysm ☐ Unknown）
☐ Intracerebral hemorrhage（Relation to aneurysm: ☐ Yes ☐ No ☐ Unknown）
☐ Cerebral infarction（Relation to aneurysm: ☐ Yes ☐ No ☐ Unknown）
☐ Cranial nerve palsy
☐ Death unrelated to UIAs

In case of rupture, register the following information:

- Status of stress when rupture occurred

Physical: ☐ Heavy-duty labor ☐ During sleep ☐ Other
Emotional: ☐ Stressed ☐ During sleep ☐ Other

- Level of consciousness at the Emergency room

Glasgow Coma Scale〔Reference table 2〕:
Best eye response: Best verbal response: Best motor response:
WFNS grade〔Reference table 3〕:

- Diagnosis of SAH

☐ CT scan ☐ Cerebrospinal fluid ☐ Autopsy ☐ None, other

- Grade of SAH（CT classification）

Fischer's classification〔Reference table 3〕
☐ I ☐ II ☐ III ☐ IV

- Last known modified Rankin scale: （Reference table 1）
- End of the study?: ☐ End ☐ Continue
- Reason for End: ☐ Aneurysm rupture ☐ Death ☐ Other

○ **Return to 36-month registration form**

Treatment record 36 months（FORM IVT）

Register if any treatment during the interim

- **UA number*:** UA
- **Hospital code:** ☐ A- ☐ C- ☐ N-
- **Name of the hospital:**
- **Patient hospital ID:**
- **Patient's name (initials only):**

- Number of aneurysms treated:

- UIA index treated: ○1○2○3○4○5
- Method of treatment:

☐ Craniotomy (Clipping, etc)
☐ Endovascular treatment
☐ Both (combined)

- Reason for treatment（Choose one reason which influenced the decision most）

☐ Desire of the patient or family
☐ Age
☐ Related to SAH
High risk of rupture（☐ Size ☐ Shape ☐ Location）
☐ Change of aneurysm (such as enlargement, etc.)
☐ Appearance of symptoms（such as cranial nerve palsy, etc.）
☐ Rupture
☐ Other

- Date of treatment: ☐☐☐☐/☐☐/
- Imaging after the treatment:

☐ Yes ☐ No

If Yes:

➢ Type of imaging: ☐ Angiography ☐ MRA, ☐ 3D CTA
➢ Effect of treatment: ☐ Complete occlusion ☐ Incomplete occlusion

（Incomplete occlusion: Residual neck after clipping or obliteration rate <90% after coiling）

Repeat 2~5 times if multiple aneurysms were treated（up to 5 times）

- Outcome/Neurological status 1 month after the treatment

1）Neurological deficits（May check multiple boxes）

☐ None ☐ Motor palsy ☐ Sensory disturbance
☐ Speech disturbance ☐ Cranial nerve deficits ☐ Disequilibrium
☐ Other

2) *Rankin scale:* ☐ (Reference table 1)

3) *Relation between neurological deficits and treatment* (if there is new neurological deficit)

☐ Yes ☐ No ☐ Unknown

- If yes, list intra- or peri-operative events most likely inducing the deficits

☐ Perforator injury ☐ Parent artery occlusion ☐Venous injury
☐ Cerebral retraction, temporary occlusion of the parent artery
☐ Intraoperative rupture ☐ Other surgical insults
☐ General complication during surgery☐ Complication after surgery

4) Other peri-operative complications ☐ Yes ☐ No

- If Yes, check below:

☐ Hydrocephalus ☐ Intracerebral hemorrhage ☐Seizure
☐ Wound infection ☐ Meningitis ☐ Olfactory disturbance
☐ Vision change ☐ Subdural hygroma, hematoma
☐ Facial frontal branch palsy ☐ Pneumonia
☐ Deep vein thrombosis of lower extremities
☐ Gastrointestinal bleeding ☐ Drug allergy ☐ Other

○Return to 36-month registration form

Image follow-up record, 36 months (FORM IVD)

Register if any imaging was obtained during the interim

- Date of imaging: ／ ／
- **UA number: UA**
- **Hospital code: ☐ A- ☐ C- ☐ N-**
- **Name of the hospital:**
- **Patient hospital ID:**
- **Patient's name (initials only):**
- Type of imaging: ☐ MRA ☐ CTA ☐ Angiography ☐ CT ☐ MRI
- Findings:

☐ Cerebral infarction ☐ Hydrocephalus ☐ Brain atrophy ☐ New aneurysm
☐ Intracerebral hemorrhage ☐ Other ☐ None

- Findings on aneurysms: ☐ Change ☐ No change
- If any change, record the following:

UIA index with any change: ○1 ○2 ○3 ○4 ○5

- Size:

☐ Same ☐ Enlargement（ mm、 %） ☐ Shrinkage（ mm、 %）
☐ Complete obliteration by the treatment
☐ Incomplete obliteration by the treatment

- Shape:

☐ Unchanged ☐ Changed

（Repeat if any changes in multiple aneurysms）

- Is the imaging obtained after treatment?: ☐ Post treatment ☐ No

Register below if this is post-treatment

- Any imaging change by the treatment: ☐ Yes ☐ No
  - ➢ Record below if yes:

☐ Cerebral infarction ☐ Brain contusion ☐Subdural hygroma ☐ Subdural hematoma
☐ Hydrocephalus ☐ Other

○Return to 36-month registration form

Final follow-up registration (FORM F) *added in Oct. 2008*

Register the patient's status more than 36 months after the initial consult (Day 0 of Form I)

- **UA number*:UA**
- Date of observation: ／ ／
- **Hospital code: ☐ A- ☐ C- ☐ N-**
- **Name of the hospital:**
- **Patient hospital ID:**
- **Patient's name (initials only):**

Blue information will be automatically indicated when registering at the online registration page.

*** UA number is the UCAS Japan patient identification number, which is assigned to each patient automatically as soon as the initial registration is recorded.**

- Change of patient's status during the interim

(such as rupture, neurological change, death, etc.):

☐ Yes ☐ No (Register FORM IIC if Yes)

  - Date of change: / /

- Any treatment during the interim:

☐ Yes ☐ No (Register FORM IIT if Yes)

  - Date of Treatment: / /

- Any imaging during the interim:

☐ Yes ☐ No (Register FORM II D if Yes)

  - Date of Imaging: / /

- Neurological Findings:

1) Neurological deficits (May check multiple boxes)

☐ None ☐ Motor palsy ☐ Sensory disturbance
☐ Speech disturbance ☐ Cranial nerve deficits ☐ Disequilibrium
☐ Other

2) Disturbed consciousness ☐ Yes ☐ No

If yes, register Glasgow Coma Scale (reference table 2):

Best Eye Response:	Best Verbal response:	Best Motor Response:

3) Modified Rankin scale: ☐ (Reference table 1)

Change record Final (FORM FC) *added in Oct. 2008*

Register if any change in patient's clinical stauts or aneurysm rupture during the interim

- **UA number:** UA
- **Hospital code:** ☐ A- ☐ C- ☐ N-
- **Name of the hospital:**
- **Patient hospital ID:**
- **Patient's name (initials only) :**
- **Date of change:** ／ ／
- **Change type**

☐ Rupture of aneurysm（☐ Recorded aneurysm: UIA index ○1○2○3○4○5)
☐ New aneurysm ☐ Unknown）
☐ Intracerebral hemorrhage（Relation to aneurysm:☐ Yes ☐ No ☐ Unknown）
☐ Cerebral infarction（Relation to aneurysm:☐ Yes ☐ No ☐ Unknown）
☐ Cranial nerve palsy
☐ Death unrelated to UIAs

In case of rupture, register the following information:

- Status of stress when rupture occurred

Physical: ☐ Heavy-duty labor ☐ During sleep ☐ Other
Emotional: ☐ Stressed ☐ During sleep ☐ Other

- Level of consciousness at the Emergency room

Glasgow Coma Scale〔Reference table 2〕:
Best eye response: Best verbal response: Best motor response:
WFNS grade〔Reference table 3〕:

- Diagnosis of SAH

☐ CT scan ☐ Cerebrospinal fluid ☐ Autopsy ☐ None, other

- Grade of SAH（CT classification）

Fischer's classification〔Reference table 3〕
☐ I ☐ II ☐ III ☐ IV

- Last known modified Rankin scale: （Reference table 1）
- End of the study?: ☐ End ☐ Continue
- Reason for End: ☐ Aneurysm rupture ☐ Death ☐ Other

○ **Return to registration form F**

Treatment record Final（FORM FT） *added in Oct. 2008*

Register if any treatment during the interim

- **UA number*:** UA
- **Hospital code:** ☐ A- ☐ C- ☐ N-
- **Name of the hospital:**
- **Patient hospital ID:**
- **Patient's name (initials only):**

- Number of aneurysms treated:

- UIA index treated: ○1○2○3○4○5
- Method of treatment:

  ☐ Craniotomy (Clipping, etc.)
  ☐ Endovascular treatment
  ☐ Both (combined)

- Reason for treatment （Choose one reason which influenced the decision most）

☐ Desire of the patient or family
☐ Age
☐ Related to SAH
High risk of rupture（☐ Size ☐ Shape ☐ Location）
☐ Change of aneurysm (such as enlargement, etc.)
☐ Appearance of symptoms（such as cranial nerve palsy, etc.）
☐ Rupture
☐ Other

- Date of treatment: ☐☐/☐☐/☐☐
- Imaging after the treatment:

☐ Yes ☐ No

If Yes:

- Type of imaging: ☐ Angiography ☐ MRA, ☐ 3D CTA
- Effect of treatment: ☐ Complete occlusion ☐ Incomplete occlusion

（Incomplete occlusion; Residual neck after clipping or obliteration rate <90% after coiling）

Repeat 2~5 times if multiple aneurysms were treated（up to 5 times）

- Outcome/Neurological status 1 month after the treatment

1）Neurological deficits（May check multiple boxes）

☐ None ☐ Motor palsy ☐ Sensory disturbance
☐ Speech disturbance ☐ Cranial nerve deficits ☐ Disequilibrium
☐ Other

2) *Rankin scale:* ☐ (Reference table 1)

3) *Relation between neurological deficits and treatment* (if there is new neurological deficit)

☐ Yes ☐ No ☐ Unknown

- If Yes, list intra- or peri-operative events most likely inducing the deficits.

☐ Perforator injury ☐ Parent artery occlusion ☐Venous injury
☐ Cerebral retraction, temporary occlusion of the parent artery
☐ Intraoperative rupture ☐ Other surgical insults
☐ General complication during surgery ☐ Complication after surgery

4) Other peri-operative complications ☐ Yes ☐ No

- If Yes, check below:

☐ Hydrocephalus ☐ Intracerebral hemorrhage ☐Seizure
☐ Wound infection ☐ Meningitis ☐ Olfactory disturbance
☐ Vision change ☐ Subdural hygroma, hematoma
☐ Facial frontal branch palsy ☐ Pneumonia
☐ Deep vein thrombosis of lower extremities
☐ Gastrointestinal bleeding ☐ Drug allergy ☐ Other

○Return to registration form F

Image follow-up record Final (FORM FD) *added in Oct. 2008*

Register if any imaging was obtained during the interim

- Date of imaging: ／ ／
- **UA number: UA**
- **Hospital code: ☐ A- ☐ C- ☐ N-**
- **Name of the hospital:**
- **Patient hospital ID:**
- **Patient's name (initials only):**
- Type of imaging: ☐ MRA ☐ CTA ☐ Angiography ☐ CT ☐ MRI
- Findings:

☐ Cerebral infarction ☐ Hydrocephalus ☐ Brain atrophy ☐ New aneurysm
☐ Intracerebral hemorrhage ☐ Other ☐ None

- Findings on aneurysms: ☐ Change ☐ No change
- If any change, record the following:

UIA index with any change: ○1 ○2 ○3 ○4 ○5

- Size:

☐ Same ☐ Enlargement（ mm、 %） ☐ Shrinkage（ mm、 %）
☐ Complete obliteration by the treatment
☐ Incomplete obliteration by the treatment

- Shape:

☐ Unchanged ☐ Changed

（Repeat if any changes in multiple aneurysms）

- Is the imaging obtained after treatment?: ☐ Post treatment ☐ No

Register below if this is post-treatment

- Any imaging change by the treatment: ☐ Yes ☐ No
  - ➢ If yes, record below:

☐ Cerebral infarction ☐ Brain contusion ☐Subdural hygroma ☐ Subdural hematoma
☐ Hydrocephalus ☐ Other

○Return to registration form F

Emergency Event Registration (FORM E)

Register if the aneurysm ruptured, the patient died, or the patient could not be followed for any reason

- UA number: **UA**
- Date of Emergency event: ／ ／
- **Hospital code**: ☐ A- ☐ C- ☐ N-
- **Name of the hospital**:
- **Patient hospital ID**:
- **Patient's name (initials only)**:

- Type of Event

☐ Rupture of the UIA（☐ Known UIA: UIA index: ○1○2○3○4○5、
☐ New aneurysm ☐ Unknown）
☐ Death other than SAH
☐ Other: Patient could no longer be followed

In cases of rupture, register following information

- Status of stress when rupture occurred

Physical: ☐ Heavy-duty labor ☐ During sleep ☐ Other
Emotional: ☐ Stressed ☐ During sleep ☐ Other

- Level of consciousness at the Emergency room

Glasgow Coma Scale〔Reference table 2〕:
Best eye response: Best verbal response: Best motor response:
WFNS grade〔Reference table 3〕:

- Diagnosis of SAH

☐ CT scan ☐ Cerebrospinal fluid ☐ Autopsy ☐ None, other

- Grade of SAH（CT classification）

Fischer's classification〔Reference table 4〕
☐ I ☐ II ☐ III ☐ IV

- Last known modified Rankin scale: (Reference table 1)
- Reason of study termination:

☐ Aneurysm rupture ☐ Death ☐ Inability to follow-up

Reference tables

Table 1: Modified Rankin Scale (modified for UCAS Japan)

Grade	Description
0	No symptoms
1	Minor symptoms that do not interfere with lifestyle
2	Minor handicap; symptoms that lead to some restriction in lifestyle but do not interfere with the patient's capacity to look after himself
3	Moderate handicap; symptoms that significantly restrict lifestyle and prevent totally independent existence
4	Moderately severe handicap; symptoms that clearly prevent independent existence though not needing constant attention
5	Severe handicap; totally dependent patient requiring constant attention night and day
6	Death

Table 2: Glasgow Coma Scale

Points	Best Eye Response	Best Verbal response	Best Motor Response
6	-	-	Obeys commands
5	-	Oriented	Localizes pain
4	Spontaneous open	Confused	Withdraw to pain
3	Open to speech	Inappropriate	Abnormal flexion (Decorticate)
2	Open to pain	Incomprehensive	Abnormal extension (Decerebrate)
1	None	None	None

Table 3: WFNS SAH grade (World Federation of Neurological Societies) grading scale

Grade	Glasgow Coma Scale	Neurologic Deficit
I	15	(-)
II	14~13	(-)
III	14~13	(+)
IV	12~7	With or without focal neurologic deficit
V	6~3	With or without abnormal posturing

Table 4: Fischer CT classification of subarachnoid hemorrhage

Group	Blood clot on CT scan
1	No blood detected
2	Diffuse or vertical layers, thickness <1mm
3	Diffuse or vertical layer, and/or localized clot, thickness ≥1mm
4	Intracerebral or intraventricular clot with diffuse or no SAH

When you find unruptured cerebral aneurysm

UCAS Japan Patient Registration Manual

1. Provide information to the patient and obtain informed consent to join this study.
2. Register Privacy form (**FORM P**) and store printed version in the study booklet.
3. Study booklet: Record new patient in the patient list. Plot follow-up schedule and past schedule on the patient medical record.
4. Online registry of the patient data using ID, Password allocated to the institution.
5. Initial Form registration; record patient's demographic data and aneurysm information **FORM I**.
6. Periodic Email reminder will be sent from the UMIN center to each investigator.
7. 3-month registration. Record patient status at the time of 3-month follow-up. Record if any change in status, treatment or image information during interim period. **FORM II** (+ FORM IIC, FORM IIT, FORM IID)
8. 12-month and 36-month registration: Record patient status at the time of 12-month or 36-month follow-up. Record if any change in status, treatment or image information during interim period.
   12 months: **FORM III** (+ FORM IIIC, FORM IIIT, FORM IIID)
   36 months: **FORM IV** (+ FORM IVC, FORM IVT, FORM IVD)
9. If the follow-up is stopped by the event of rupture, death or other reason (such as patient's transfer, loss to follow-up or refusal, etc.), registration can be finished for the patient at any time by recording emergency form, **FORM E.**
10. Transmission of data by facsimile to the coordinating office is allowed.

UCAS Japan Coordinating Office
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