**Intravenous Magnesium sulfate in Aneurysmal Subarachnoid Hemorrhage**

The IMASH trial is a simple, randomized, double-blinded, placebo-controlled multi-center trial to answer the question: “Does intravenous magnesium sulfate improve clinical outcome after aneurysmal subarachnoid hemorrhage?”

**Case Report Form**

Version 3.1; 1 March, 2003

**Patient Trial Number:**

[Blank fields for Center code and Patient number]

**Patient initial:**

[Blank fields for initial]

**Investigator Name:**

[Blank space for name]

**Center Name:**

[Blank space for name]

**Coordinating Center:** Division of Neurosurgery, Department of Surgery, Chinese University of Hong Kong, Prince of Wales Hospital, Shatin, NT, Hong Kong
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Fax: +852 2646 9296
DataFax: +852 26469296
www.surgery.cuhk.edu.hk/imash-trial
Patient Contact Form

Patient Information

Patient Name: ___________________ ___________________ ___________________
  Last Name                               First Name                               Middle Name

Maiden Name (if applicable)

Address: ___________________   ___________________
  Apt/House/Block No.                   Street                   Zip/Postal code (enter “0” in the first box if no Zip/Postal code required)

City                                           Province                                           Country

Telephone Number: ___________________   ___________________
  Area code                                           ___________________                                           ___________________

Alternate phone number: ___________________   ___________________
  Area code                                           ___________________                                           ___________________

Hospital (or patient identification) number: ___________________   ___________________   ___________________

Other Contact (Close friend or family member who may be able to provide follow–up information)

Contact Name: ___________________ ___________________ ___________________
  Last Name                               First Name                               Middle Name

Address: ___________________   ___________________
  Apt/House No.                   Street                   Zip/Postal code (enter “0” in the first box if no Zip/Postal code required)

City                                           Province                                           Country

Telephone Number: ___________________   ___________________
  Area code                                           ___________________                                           ___________________

Alternate phone number: ___________________   ___________________
  Area code                                           ___________________                                           ___________________
General comments

Please ensure every question is answered. Make sure the center code and patient number is entered in each page.

Please write clearly, within the boxes and in **BLOCK** letter for each field, or fill in circles to indicate appropriate response. Enter zero in first box for each item not requiring data to indicate that the question has not been overlooked.

\[ \text{e.g. } \boxed{0} . \boxed{.} \text{ mg} \]

To correct errors: draw a line through entire field and write correct entry above or beside error. Initial and date the change. E.g. \[ \text{2010} \]
\[ L \ C 10/04/2003 \]

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Q.3 Body Weight - please estimate the body weight if the exact body weight could not be obtained.

Q.7 Time of Hemorrhage events - if the exact time of hemorrhage events (ictus) could not be obtained, write the estimated time.

Q.8 Time of hospital admission, please enter the time of the patient’s first hospitalization.

Q.9 Verbal score - please write “T” if the patient’s trachea is intubated.

Q.14 Please circle **CTA, MRA** or **DSA** to indicate where aneurysms were seen.

Q.15 Size of the ruptured aneurysm - please write the maximal diameter of the size of the ruptured aneurysm.
Baseline information

1. Randomization date / time: \( \text{d} / \text{m} / \text{y} \) \( \text{h} : \text{m} \) \( 24 \) h clock

2. Gender (\( \square \) one appropriate box): \( \square \) Male \( \square \) Female

3. Weight: \( \square \) kg (whole number, estimated)

4. Ethnicity (\( \square \) one appropriate box): \( \square \) Asian \( \square \) White \( \square \) Black \( \square \) Indian

5. Date of birth: \( \text{d} / \text{m} / \text{y} \)

6. Co–morbidity: (\( \square \) all appropriate box(es))
   - None
   - Diabetes Mellitus
   - Coagulopathy
   - Previous stroke / TIA
   - Current smoker
   - COAD
   - Arrhythmia
   - Hyperlipidemia
   - Hypertension
   - Liver disease
   - Ischemic heart disease
   - Renal impairment
   - Others

Information on the ruptured aneurysm

7. Time of hemorrhage events (ictus): \( \text{d} / \text{m} / \text{y} \) \( \text{h} : \text{m} \) \( 24 \) h clock

8. Time of hospital admission: \( \text{d} / \text{m} / \text{y} \) \( \text{h} : \text{m} \) \( 24 \) h clock

9. Glasgow Coma Scale on admission:
   - Eye score (1 – 4)
   - Motor score (1 – 6)
   - Verbal score (1 – 5) or T for intubation

10. Was there cranial nerve deficit? (\( \square \) One box only) \( \square \) No \( \square \) Yes

11. In the admission plain CT, was there:
    (\( \square \) One box only for each question)
    - Hydrocephalus? \( \square \) \( \square \)
    - Intraventricular clot? \( \square \) \( \square \)
    - Intracerebral clot? \( \square \) \( \square \)

12. Pre-randomization events causing clinical deterioration:
    - Aneurysmal rebleeding? \( \square \) \( \square \)
    - Seizure? \( \square \) \( \square \)
    - Hydrocephalus? \( \square \) \( \square \)

13. In the admission plain CT, how extensive was the SAH? (Fisher’s grade) (\( \square \) one box only)
    - None or minimal SAH
    - Diffuse thin SAH (\( \leq 1 \) mm in thickness over the entire length of a cistern or fissure)
    - Large clot or thick layer of SAH (\( > 1 \) mm in thickness over the entire length of a cistern or fissure)
    - Diffuse thin or no SAH, with significant ICH or IVH

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14. How many aneurysm(s) were seen in the CTA or MRA or DSA .......... (Whole number)

15. What was the size of the ruptured aneurysm? .......... mm (measured from the maximal diameter)

16. Where was the ruptured aneurysm? (☐ all appropriate box(es))

- Right
- Left
- Midline
- Anterior cerebral artery territory ....... AComA
- Pericallosal A
- Pericallosal A
- Proximal to AComA
- Basilar bifurcation
- Distal to bifurcation
- Proximal to bifurcation
- Basilar trunk
- Posterior cerebral A
- Superior cerebellar A
- Internal carotid artery territory ....... PComA
- Bifurcation
- Proximal to Ophthalmic A

17. Modified National Institute of Health Stroke Scale (mNIHSS)

Enter the score in the boxes, see procedure manual for scoring instruction

<table>
<thead>
<tr>
<th>1B Questions</th>
<th>1C Commands</th>
<th>2 Gaze</th>
<th>3 Visual fields</th>
<th>5a Left arm motor</th>
<th>5b Right arm motor</th>
<th>6a Left leg motor</th>
<th>6b Right leg motor</th>
<th>8 Sensory</th>
<th>9 Language</th>
<th>11 Neglect</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 = Answers both correctly, Alert</td>
<td>0 = Performs both tasks correctly</td>
<td>0 = Normal</td>
<td>0 = No visual loss</td>
<td>0 = No drift</td>
<td>0 = No drift</td>
<td>0 = No drift</td>
<td>0 = No drift</td>
<td>0 = Normal</td>
<td>0 = Normal</td>
<td></td>
</tr>
<tr>
<td>1 = Answers one correctly</td>
<td>1 = Performs one task correctly</td>
<td>1 = Partial gaze palsy</td>
<td>1 = Partial hemianopsia</td>
<td>1 = Drift before 5 seconds</td>
<td>1 = Drift before 5 seconds</td>
<td>1 = Drift before 5 seconds</td>
<td>1 = Drift before 5 seconds</td>
<td>1 = Mild aphasia</td>
<td>1 = Mild</td>
<td></td>
</tr>
<tr>
<td>2 = Answers neither correctly</td>
<td>2 = Performs neither task</td>
<td>2 = Total gaze palsy</td>
<td>2 = Complete hemianopsia</td>
<td>2 = Falls before 5 seconds</td>
<td>2 = Falls before 5 seconds</td>
<td>2 = Falls before 5 seconds</td>
<td>2 = Falls before 5 seconds</td>
<td>2 = Severe aphasia</td>
<td>2 = Severe</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 = Bilateral hemianopsia</td>
<td>3 = No effort against gravity</td>
<td>3 = No effort against gravity</td>
<td>3 = No effort against gravity</td>
<td>3 = No effort against gravity</td>
<td>3 = Mute or global aphasia</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4 = No movement</td>
<td>4 = No movement</td>
<td>4 = No movement</td>
<td>4 = No movement</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Q.20 Enter the start time for the first procedure only

Q. 21 Estimate the duration of temporary artery clipping
# Surgical Treatment

18. Was nimodipine given?  

19. Has the patient received:  
   - Hypertensive therapy?  
   - Hemodilution?  
   - Hypervolemia?  

20. What surgical treatment was performed?  
   - Surgical clipping  
   - Endovascular coiling  
   - None

   If yes, please state reason: ________________________________

21. Procedure start time:  
   -  

22. Was temporary clip used? (for clipping only)  
   - Yes  
   - No

   If yes, how long was the proximal artery temporarily clipped?  
   - _____ min

23. Was pharmacologic protection provided?  
   - Yes  
   - No

   If yes, what drug was used?  
   - Thiopental  
   - Propofol  
   - Others: ________________________________

24. Was hypothermia provided?  
   - Yes  
   - No

   If yes, what was the average temperature?  
   - _____ °C

25. Was the aneurysm:  
   - Completely occluded?  
   - Partially occluded?

26. Complications during the procedure?  
   - Brain swelling?  
   - Rupture of aneurysm?
Guide to Page B1

Q.2 If the patient died before discharge, please leave the date of hospital discharge “Blank” and complete “DEATH REPORT”.

Q.5 Record the study drug infusion, TCD and plasma magnesium data:

Day 0 is the day of hemorrhage. You must start study drug by day 2, otherwise the patient do not fulfill entry criteria.

TCD is optional, record the maximum flow velocity only (right or left, whichever is higher).

Record the maximum daily [Mg²⁺] (if this was measured more than once).

Record the total volume of study drug infused. Study drug should contain MgSO₄ 80 mmol or Equal volume of saline in 500 ml fluid.
(The bolus study drug given at the start of the study should not be counted)

Stop the infusion in completely asymptomatic cases after Day 10 post bleed; otherwise the study drug should be discontinued on Day 14 after SAH. If there is ongoing evidence of clinical vasospasm, the infusion will be continued until the period of clinical vasospasm resolves/stabilizes.

If the study drug has been stopped due to Serious Adverse Event (SAE), please complete an SAE form.
1. Date of hospital discharge? [ ] No [ ] Yes  
(24 h clock)

2. Was the patient:  
[ ] Discharged home?  
[ ] Transferred to long-term care or rehabilitation facility?  
[ ] Died?  
(One box for each question)

3. Study drug infusion:  
3a. When was study drug started? [ ] No [ ] Yes  
(24 h clock)  

4a. Has study drug been stopped?  
[ ] No [ ] Yes  
If yes, why? ________________________________  
(Please complete an SAE form if necessary)

4b. Has study drug been adjusted?  
[ ] No [ ] Yes  
If yes, increased [ ] decreased [ ]  

5. Record daily study drug infusion, TCD and plasma magnesium data:  

<table>
<thead>
<tr>
<th>Date (d d / m m / y y)</th>
<th>Mean MCA or ACA FV</th>
<th>Plasma Mg conc.</th>
<th>Total volume of study drug infused (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>cm/s Hz</td>
<td>mg/dL mmol/L</td>
<td></td>
</tr>
<tr>
<td>Day 0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 1</td>
<td></td>
<td></td>
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<tr>
<td>Day 2</td>
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<td>Day 3</td>
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<td>Day 4</td>
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<td>Day 5</td>
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<td>Day 6</td>
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<td>Day 7</td>
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<td>Day 8</td>
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<td></td>
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<tr>
<td>Day 9</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Day 10</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Study drug must start within 48h of hemorrhagic events)

Complete DEATH Report
Definitions:

Episodes of **CLINICAL VASOSPASM** are defined as (i) a drop in Glasgow Coma Scale (GCS) Score of more than one for more than six hours, or (ii) focal neurological deficits such as hemiparesis not caused by:

1. rebleed (as confirmed by CT scan)
2. progressive hydrocephalus (as confirmed by CT scan)
3. electrolyte or metabolic disturbance

Possible neurological events related to ASAH:

1. rebleed (as confirmed by CT scan)
2. seizure (EEG or clinical convulsion)
3. hydrocephalus (as confirmed by CT scan and requiring VP shunts and/or lumbar puncture)
4. cerebral infarction (as confirmed by CT scan with or without neurological deficit)
5. post treatment (coiling or surgery) sequela (as confirmed by history and/or CT scan)

Myocardial infarction - confirmed by ECG and/or troponin (cTnT or cTnI) or CK-MB enzyme rise

Venous thromboembolism (DVT or PE) - confirmed by venography, duplex ultrasonography, V-Q scan or spiral CT, or autopsy

Pneumonia - two or more of temperature > 38 °C, white cell count > 12,000/ml, and positive sputum culture

Acute renal failure - plasma creatinine > 200 µmol/L or twice the preoperative value

Sepsis - new postoperative infection, positive microbial culture, requiring antibiotics

Cardiac failure - any of the following signs (elevated jugular venous pressure, respiratory rates, crepitations, or presence of S3) plus radiographic evidence (e.g. vascular redistribution, interstitial pulmonary edema, or frank alveolar pulmonary edema)

Gastrointestinal bleed - confirmed by endoscopy

Arrhythmia (not related to myocardial ischemia) - include arrhythmia that required treatment (e.g. antiarrhythmics or pacing) only

Hypotension - persistent systolic blood pressure < 90 mmHg requiring vasopressor or inotropes and is not related to septic shock

Abnormal electrolytes - include symptomatic hyper- or hyponatremia requiring treatment (e.g. hypertonic saline, dDAVP, water infusion, …)
<table>
<thead>
<tr>
<th>Date</th>
<th>Mean MCA or ACA FV cm/s Hz</th>
<th>Plasma Mg conc. mg/dL mmol/L</th>
<th>Total volume of study drug infused (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 11</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Day 12</td>
<td></td>
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<td></td>
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<tr>
<td>Day 13</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Day 14</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. Number of days in Intensive care unit / high dependency unit? __________ Days
7. Number of days required ventilation (IPPV, biPAP)? __________ Days

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**CLINICAL EVENTS (since randomization)**

8. Vasospasm
9. Other neurological events:
   a. Aneurysm re–bleeding
   b. Hydrocephalus
   c. Seizure
   d. CNS infection, if yes, what was the primary organism?
10. Cerebral ischemia/infarction/hemorrhage not related to vasospasm
    a. Raised ICP / cerebral edema
    b. Procedure related cerebral hematoma
11. Extracranial events
    a. Pneumonia
    b. Sepsis (other than pneumonia)
    c. Myocardial infarct
    d. Arrhythmia (not related to myocardial ischemia)
    e. Cardiac failure
    f. Deep vein thrombosis
    g. Pulmonary embolism
    h. Gastrointestinal bleeding
    i. Abnormal electrolytes
    j. Hypotension (requiring vasopressor or inotropes)
    k. Acute renal failure
    l. Others: ___________________________________________

(Please write in BLOCK letter)

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Continue page B3
12. Did patient require more surgery?  
   [ ] No  [ ] Yes

   If yes, what surgery has been performed? ____________________________________________
   (Please enter the date of the operation)

13. Record the discharge Modified National Institute of Health Stroke Scale (mNIHSS)

   Enter the score in the boxes, see procedure manual for scoring instruction

<table>
<thead>
<tr>
<th>Question</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1B Questions</td>
<td>0</td>
<td>Answers both correctly, Alert</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Answers one correctly</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Answers neither correctly</td>
</tr>
<tr>
<td>1C Commands</td>
<td>0</td>
<td>Performs both tasks correctly</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Performs one task correctly</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Performs neither task</td>
</tr>
<tr>
<td>2 Gaze</td>
<td>0</td>
<td>Normal</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Partial gaze palsy</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Total gaze palsy</td>
</tr>
<tr>
<td>3 Visual fields</td>
<td>0</td>
<td>No visual loss</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Partial hemianopsia</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Complete hemianopsia</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Bilateral hemianopsia</td>
</tr>
<tr>
<td>5a Left arm motor</td>
<td>0</td>
<td>No drift</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Drift before 10 seconds</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Falls before 10 seconds</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>No effort against gravity</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>No movement</td>
</tr>
<tr>
<td>5b Right arm motor</td>
<td>0</td>
<td>No drift</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Drift before 10 seconds</td>
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<tr>
<td></td>
<td>2</td>
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<td>3</td>
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<td>4</td>
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<td>0</td>
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<td>3</td>
<td>No effort against gravity</td>
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<tr>
<td></td>
<td>4</td>
<td>No movement</td>
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<tr>
<td>8 Sensory</td>
<td>0</td>
<td>Normal</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Abnormal</td>
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<tr>
<td>9 Language</td>
<td>0</td>
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</tr>
<tr>
<td></td>
<td>1</td>
<td>Mild aphasia</td>
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<tr>
<td></td>
<td>2</td>
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<td>3</td>
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<tr>
<td>11 Neglect</td>
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<td>Normal</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Severe</td>
</tr>
</tbody>
</table>

Fax B1–B3 to +852 26469296
within 48 hours after discharge
If the patient died before 3 month follow-up, please leave the date of 3 month follow-up page blank

Q.2 If the patient has been re-hospitalized for more than once, please enter the first re-hospitalization only. If the patient admits for CT scan, it is not necessary to count as re-hospitalized

Q.3 Death – please complete the death report if the patient died within 6 month follow-up period
1. Date of 3 months follow up: 

2. Has patient been re–hospitalized since discharge? 
   (One box only) 
   No ☐ Yes ☐ 

   If yes, when was the date of admission? 
   d d / m m / y y 

   What was? 

   Primary diagnosis? ________________________________ 

   Secondary diagnosis? ________________________________ 

CLINICAL EVENTS (since hospital discharge) 
(One box for each question)

3. Death ☐ ☐ Complete DEATH Report 

4. Neurological events: 
   a. Cerebral hemorrhage. ☐ ☐ 
   b. Cerebral infarction. ☐ ☐ 
   c. Hydrocephalus. ☐ ☐ 
   d. Seizure. ☐ ☐ 
   e. CNS infection. ☐ ☐ 
   f. Others: ________________________________ 

5. Extracranial events 
   a. Pneumonia ☐ ☐ 
   b. Sepsis (other than pneumonia). ☐ ☐ 
   c. Myocardial infarct. ☐ ☐ 
   d. Arrhythmia (not related to myocardial ischemia). ☐ ☐ 
   e. Cardiac failure. ☐ ☐ 
   f. Deep vein thrombosis. ☐ ☐ 
   g. Pulmonary embolism. ☐ ☐ 
   h. Gastrointestinal bleeding. ☐ ☐ 
   i. Others: ________________________________ 
   (Please write in BLOCK letter)
6. **Barthel Index**
*Enter the score in the boxes, see procedure manual for scoring instruction*

<table>
<thead>
<tr>
<th>FEEDING</th>
<th>0 = unable</th>
<th>5 = needs help cutting, spreading butter, etc., or requires modified diet</th>
<th>10 = independent</th>
</tr>
</thead>
<tbody>
<tr>
<td>BATHING</td>
<td>0 = dependent</td>
<td>5 = independent (or in shower)</td>
<td></td>
</tr>
<tr>
<td>GROOMING</td>
<td>0 = needs to help with personal care</td>
<td>5 = independent face/hair/teeth/shaving (implements provided)</td>
<td></td>
</tr>
<tr>
<td>DRESSING</td>
<td>0 = dependent</td>
<td>5 = needs help but can do about half unaided</td>
<td>10 = independent (including buttons, zips, laces, etc.)</td>
</tr>
<tr>
<td>BOWELS</td>
<td>0 = incontinent (or needs to be given enema)</td>
<td>5 = occasional accident</td>
<td>10 = continent</td>
</tr>
<tr>
<td>BLADDER</td>
<td>0 = incontinent, or catheterized and unable to manage alone</td>
<td>5 = occasional accident</td>
<td>10 = continent</td>
</tr>
</tbody>
</table>

**TOILET USE**

| 0 = dependent | 5 = needs some help, but can do something alone | 10 = independent (on and off, dressing, wiping) |

**TRANSFERS (BED TO CHAIR AND BACK)**

| 0 = unable, no sitting balance | 5 = major help (one or two people, physical), can sit | 10 = minor help (verbal or physical) |
| 15 = independent |

**MOBILITY (ON LEVEL SURFACES)**

| 0 = immobile or < 50 yards | 5 = wheelchair independent, including corners, > 50 yards |
| 10 = walks with help of one person (verbal or physical) > 50 yards |
| 15 = independent (but may use any aid; for example, stick) > 50 yards |

**STAIRS**

| 0 = unable | 5 = needs help (verbal, physical, carrying aid) | 10 = independent |

7. **Modified Rankin Scale**
*(One box only)*

| 0 = No symptoms |
| 1 = Minor symptoms that do not interfere with lifestyle |
| 2 = Minor handicap: symptoms that lead to some restriction in lifestyle |
| 3 = Moderate handicap: symptoms that significantly restrict lifestyle and require help |
| 4 = Severe handicap: symptoms that clearly prevent independence |
| 5 = Severe handicap: totally dependent, needing constant care |
### 8. Glasgow Outcome Scale–Extended

#### CONSCIOUSNESS
1. Is the patient able to obey simple commands, or say any words?  
   - 1 = No (VS)  
   - 2 = Yes

#### INDEPENDENCE AT HOME
2a. Is the assistance of another person at home essential every day for some activities of daily living?  
   - 1 = No  
   - 2 = Yes

2b. Do they need frequent help or someone to be around at home most of the time?  
   - 1 = No (Upper SD)  
   - 2 = Yes (Lower SD)

2c. Was assistance at home essential before SAH?  
   - 1 = No  
   - 2 = Yes

#### INDEPENDENCE OUTSIDE HOME
3a. Are they able to shop without assistance?  
   - 1 = No (Upper SD)  
   - 2 = Yes

3b. Were they able to shop without assistance before SAH?  
   - 1 = No  
   - 2 = Yes

4a. Are they able to travel locally without assistance  
   - 1 = No (Upper SD)  
   - 2 = Yes

4b. Were they able to travel without assistance before the injury?  
   - 1 = No  
   - 2 = Yes

5a. Are they currently able to work to their previous capacity?  
   - 1 = No  
   - 2 = Yes

5b. How restricted are they?  
   - a) Reduced work capacity  
   - b) Able to work only in a sheltered workshop or non-competitive job, or currently unable to work

5c. Were they either working or seeking employment before SAH?  
   - 1 = No  
   - 2 = Yes

#### SOCIAL & LEISURE ACTIVITIES
6a. Are they able to resume regular social and leisure activities outside home before SAH?  
   - 1 = No  
   - 2 = Yes

6b. What is the extent of restriction on their social and leisure activities?  
   - a) Participate a bit less: at least half as often as before SAH  
   - b) Participate much less: less than half as often  
   - c) Unable to participate: rarely, if ever, take part

6c. Did they engage in regular social and leisure activities outside home before SAH?  
   - 1 = No  
   - 2 = Yes

#### FAMILY & FRIENDSHIP
7a. Have there been psychological problems which have resulted in ongoing family disruption or disruption to friendships?  
   - 1 = No  
   - 2 = Yes

7b. What has been the extent of disruption or strain?  
   - a) Occasional—less than weekly  
   - b) Frequent—once a week or more, but tolerable  
   - c) Constant—daily and intolerable

7c. Were there problems with family or friends before SAH?  
   - 1 = No  
   - 2 = Yes

#### RETURN TO NORMAL LIFE
8a. Are there any other current problems relating to SAH which affect daily life?  
   - 1 = No (Upper GR)  
   - 2 = Yes (Lower GR)

8b. Were similar problems present before SAH?  
   - 1 = No  
   - 2 = Yes

### What Is The Most Important Factor In Outcome? (One box only)
- Effects of SAH
- Effects of illness to another part of the body
- A mixture of both

| 1 | Dead |
| 2 | Vegetative State (VS) |
| 3 | Lower Severe Disability (Lower SD) |
| 4 | Upper Severe Disability (Upper SD) |
| 5 | Lower Moderate Disability (Lower MD) |
| 6 | Upper Moderate Disability (Upper MD) |
| 7 | Lower Good Recovery (Lower GR) |
| 8 | Upper Good Recovery (Upper GR) |

The patient’s overall rating is based on the lowest outcome category indicated on the scale. Refer to guidelines for further information concerning administration and scoring (enter a score 1 to 8).
If the patient died before 6 month follow-up, please leave the date of 6 month follow-up page blank.

Q.2 If the patient has been re-hospitalized for more than once, please enter the first re-hospitalization only. If the patient admits for CT scan, it is not necessary to count as re-hospitalized.

Q.3 Death – please complete the death report if the patient died within 6 month follow-up period.
1. Date of 6 months follow up: _________________________________
2. Has patient been re–hospitalized since discharge?  
   (☐ one box only)  
   If yes, when was the date of admission?  
   _________________________________
What was?  
   Primary diagnosis?  
   Secondary diagnosis?  

CLINICAL EVENTS (since last follow–up)  
(☐ one box for each question)
3. Death ........................................................................

4. Neurological events:  
   a. Cerebral hemorrhage ............................................
   b. Cerebral infarction ...............................................  
   c. Hydrocephalus .....................................................
   d. Seizure ................................................................
   e. CNS infection ......................................................
   f. Others ..................................................................
   if yes, what was the primary organism?  
   _________________________________

5. Extracranial events  
   j. Pneumonia ............................................................
   k. Sepsis (other than pneumonia)  
   l. Myocardial infarct. .................................................
   m. Arrhythmia (not related to myocardial ischemia)  
   n. Cardiac failure .....................................................
   o. Deep vein thrombosis ..........................................  
   p. Pulmonary embolism ............................................
   q. Gastrointestinal bleeding ...................................
   r. Others: ................................................................
   (Please write in BLOCK letter)

Continue page D2
6. Barthel Index  
*Enter the score in the boxes, see procedure manual for scoring instruction*

<table>
<thead>
<tr>
<th>FEEDING</th>
<th>0 = unable</th>
<th>TOILET USE</th>
<th>0 = dependent</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 = needs help cutting, spreading butter, etc., or requires modified diet</td>
<td>5 = needs some help, but can do something alone</td>
<td>10 = independent (on and off, dressing, wiping)</td>
<td></td>
</tr>
<tr>
<td>10 = independent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BATHING</td>
<td>0 = dependent</td>
<td>TRANSFERS</td>
<td>0 = unable, no sitting balance</td>
</tr>
<tr>
<td></td>
<td>5 = independent (or in shower)</td>
<td>(BED TO CHAIR AND BACK)</td>
<td>5 = major help (one or two people, physical), can sit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 = minor help (verbal or physical)</td>
<td>15 = independent</td>
</tr>
<tr>
<td>GROOMING</td>
<td>0 = needs to help with personal care</td>
<td>MOBILITY</td>
<td>0 = immobile or &lt; 50 yards</td>
</tr>
<tr>
<td></td>
<td>5 = independent face/hair/teeth/shaving (implements provided)</td>
<td>(ON LEVEL SURFACES)</td>
<td>5 = wheelchair independent, including corners, &gt; 50 yards</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 = independent</td>
<td>10 = walks with help of one person (verbal or physical) &gt; 50 yards</td>
</tr>
<tr>
<td>DRESSING</td>
<td>0 = dependent</td>
<td>STAIRS</td>
<td>0 = unable</td>
</tr>
<tr>
<td></td>
<td>5 = needs help but can do about half unaided</td>
<td>5 = needs help (verbal, physical, carrying aid)</td>
<td>10 = independent</td>
</tr>
<tr>
<td></td>
<td>10 = independent (including buttons, zips, laces, etc.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BOWELS</td>
<td>0 = incontinent (or needs to be given enema)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 = occasional accident</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 = continent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BLADDER</td>
<td>0 = incontinent, or catheterized and unable to manage alone</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 = occasional accident</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 = continent</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. Modified Rankin Scale  
(one box only)

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No symptoms</td>
</tr>
<tr>
<td>1</td>
<td>Minor symptoms that do not interfere with lifestyle</td>
</tr>
<tr>
<td>2</td>
<td><strong>Minor handicap</strong>: symptoms that lead to some restriction in lifestyle</td>
</tr>
<tr>
<td>3</td>
<td><strong>Moderate handicap</strong>: symptoms that significantly restrict lifestyle and require help</td>
</tr>
<tr>
<td>4</td>
<td><strong>Severe handicap</strong>: symptoms that clearly prevent independence</td>
</tr>
<tr>
<td>5</td>
<td><strong>Severe handicap</strong>: totally dependent, needing constant care</td>
</tr>
</tbody>
</table>
### Glasgow Outcome Scale–Extended

**CONSCIOUSNESS**
1. Is the patient able to obey simple commands, or say any words?
   - 1 = No (VS)
   - 2 = Yes

**INDEPENDENCE AT HOME**
2a. Is the assistance of another person at home essential every day for some activities of daily living?
   - 1 = No
   - 2 = Yes

2b. Do they need frequent help or someone to be around at home most of the time?
   - 1 = No (Upper SD)
   - 2 = Yes (Lower SD)

2c. Was assistance at home essential before SAH?
   - 1 = No
   - 2 = Yes

**INDEPENDENCE OUTSIDE HOME**
3a. Are they able to shop without assistance?
   - 1 = No (Upper SD)
   - 2 = Yes

3b. Were they able to shop without assistance before SAH?
   - 1 = No
   - 2 = Yes

4a. Are they able to travel locally without assistance?
   - 1 = No (Upper SD)
   - 2 = Yes

4b. Were they able to travel without assistance before the injury?
   - 1 = No
   - 2 = Yes

5a. Are they currently able to work to their previous capacity?
   - 1 = No
   - 2 = Yes

5b. How restricted are they?
   - (a) Reduced work capacity
   - (b) Able to work only in a sheltered workshop or non-competitive job, or currently unable to work
   - 1 = a (Upper MD)
   - 2 = b (Lower MD)

5c. Were they either working or seeking employment before SAH?
   - 1 = No
   - 2 = Yes

**SOCIAL & LEISURE ACTIVITIES**
6a. Are they able to resume regular social and leisure activities outside home?
   - 1 = No
   - 2 = Yes

6b. What is the extent of restriction on their social and leisure activities?
   - (a) Participate a bit less: at least half as often as before SAH
   - (b) Participate much less: less than half as often
   - (c) Unable to participate: rarely, if ever, take part
   - 1 = a (Lower GR)
   - 2 = b (Upper MD)
   - 3 = c (Lower MD)

6c. Did they engage in regular social and leisure activities outside home before SAH?
   - 1 = No
   - 2 = Yes

**FAMILY & FRIENDSHIP**
7a. Have there been psychological problems which have resulted in ongoing family disruption or disruption to friendships?
   - 1 = No
   - 2 = Yes

7b. What has been the extent of disruption or strain?
   - (a) Occasional—less than weekly
   - (b) Frequent—once a week or more, but tolerable
   - (c) Constant—daily and intolerable
   - 1 = a (Lower GR)
   - 2 = b (Upper MD)
   - 3 = c (Lower MD)

7c. Were there problems with family or friends before SAH?
   - 1 = No
   - 2 = Yes

**RETURN TO NORMAL LIFE**
8a. Are there any other current problems relating to SAH which affect daily life?
   - 1 = No (Upper GR)
   - 2 = Yes (Lower GR)

8b. Were similar problems present before SAH?
   - 1 = No
   - 2 = Yes

---

**What Is The Most Important Factor In Outcome?** (One box only)
- Effects of SAH
- Effects of illness to another part of the body
- A mixture of both

---

<table>
<thead>
<tr>
<th>1</th>
<th>Dead</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Vegetative State (VS)</td>
</tr>
<tr>
<td>3</td>
<td>Lower Severe Disability (Lower SD)</td>
</tr>
<tr>
<td>4</td>
<td>Upper Severe Disability (Upper SD)</td>
</tr>
<tr>
<td>5</td>
<td>Lower Moderate Disability (Lower MD)</td>
</tr>
<tr>
<td>6</td>
<td>Upper Moderate Disability (Upper MD)</td>
</tr>
<tr>
<td>7</td>
<td>Lower Good Recovery (Lower GR)</td>
</tr>
<tr>
<td>8</td>
<td>Upper Good Recovery (Upper GR)</td>
</tr>
</tbody>
</table>

The patient’s overall rating is based on the lowest outcome category indicated on the scale. Refer to guidelines for further information concerning administration and scoring (enter a score 1 to 8).

Fax D1–D3 to +852 26469296 within 48 hours after follow-up
Guide to Vasospasm Report

Q.1 Enter the onset and resolution of vasospasm.

Q.2 Enter what were the presentation.

Q.3 Enter what treatment was provided.

Q.4 Enter the resolution of Vasospasm.

Q.5 Enter what was the outcome?

Write clearly and in BLOCK LETTER and complete all information before fax.

Fax the vasospasm report to 852-26469296.
1. Onset of vasospasm: 

2. What were the presentations?
   (a) Decrease in GCS by 2 points………………………….
   (b) Angiographic evidence………………………………….
   (c) Focal deficit……………………………………………….
   (d) Brain swelling…………………………………………….
   (e) Raised intracranial pressure…………………………..
   (f) Increase in MCA flow velocity…………………………

   If yes, what was the maximum MCA FV?
   What was the extracranial ICA FV?

3. What treatment was provided?
   (a) Hypertension……………………………………………….
   (b) Hypervolemia…………………………………………….
   (c) Hemodilution……………………………………………..
   (d) Endovascular angioplasty…………………………….
   (e) Vasodilator infusion……………………………………
   (f) Others: _____________________________________________________________________

4. Resolution of Vasospasm: 

5. What was the outcome?
   (a) Completely resolved (without deficit)……………………...
   (b) Cerebral infarction (with or without deficit)………………
   (c) Permanent neurological deficit………………………….
   (d) Death……………………………………………………

Complete DEATH Report

Fax this page to +852 26469296
Guide to Death Report

Q.1 Enter the time of certified death.

Q.2 Enter the causes of death.

Q.3 Enter the extracranial cause.

Please write clearly and in BLOCK LETTER and complete all information before fax.
Fax the DEATH REPORT to 852-26469296.
1. Time of certified death: 
   `dd/mm/yyyy hh:mm` (24 h clock)

2. Causes of death: (One box only for each question)

   **Neurological Cause:**
   - (a) Cerebral hemorrhage
   - (b) Cerebral infarction
   - (c) Hydrocephalus
   - (d) Status epilepticus
   - (e) CNS infection
   - (f) Others

   *if yes, what was the primary organism? ________________________________________________

   (Please write in BLOCK letter)

3. Extracranial Cause (One box only for each question)

   - (a) Pneumonia
   - (b) Sepsis (other than pneumonia)
   - (c) Myocardial infarct
   - (d) Arrhythmia (not related to myocardial ischemia)
   - (e) Cardiac failure
   - (f) Deep vein thrombosis
   - (g) Pulmonary embolism
   - (h) Gastrointestinal bleeding
   - (i) Others: ________________________________________________

   (Please write in BLOCK letter)

4. Unknown Cause: (specify)

   ________________________________________________

   (Please write in BLOCK letter)
Q.6 if the patient died due to the Serious Adverse Event, complete the DEATH REPORT.

Write clearly and in BLOCK LETTER and complete all information before fax.
Please fax SAE report to 852-26469296.
SAE is NOT part of natural history of the condition or a primary or secondary outcome of this trial

1. This serious adverse event is defined as:
   - Fatal
   - Life threatening
   - Requiring or prolonging hospitalization
   - Others (specify) ____________________________

2. Adverse Event:
   (a) Date of onset: ____________________________ (24 h clock)
   (b) What was the main diagnosis or symptom: _____________________________________________
   (c) Intensity: ___________________ mild          Moderate          Severe
   (d) Provide detailed description: ________________________________________________________

3. Study Drug Information
   (a) Was the patient on study drug all the time of the event? No  Yes
   (b) Was the study medication unblinded? No  Yes
   (c) List other relevant medications used within 24 hours of the event:
       1. ____________________________________________
       2. ____________________________________________
       3. ____________________________________________

4. Action Taken
   - No change
   - Dosage change, infusion changed to ______ ml/h
   - Study drug temporarily discontinued ____________________________
   - Study drug permanently discontinued ____________________________

5. Relationship to study drug:
   - None          Unlikely          Likely          Unknown

6. Outcome of this serious adverse event:
   - Unknown
   - Recovered with sequelae
   - Ongoing
   - Recovered without sequelae
   - Death Complete DEATH Report

Fax this page to +852 26469296