Main

Note: This record shows only 22 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register:	JPRN
Last refreshed on:	6 April 2022
Main ID:	JPRN-UMIN000014696
Date of registration:	29/07/2014
Prospective Registration:	Yes
Primary sponsor:	Department of Neurosurgery, National Defense Medical College
Public title:	Effects of intravenous infusion of hydrogen-rich fluid combined with intra-cisternal infusion of magnesium sulfate in severe aneurysmal subarachnoid hemorrhage: a randomized controlled trial
Scientific title:	Effects of intravenous infusion of hydrogen-rich fluid combined with intra-cisternal infusion of magnesium sulfate in severe aneurysmal subarachnoid hemorrhage: a randomized controlled trial - Effects of intravenous infusion of hydrogen-rich fluid combined with intra-cisternal infusion of magnesium sulfate in severe aneurysmal subarachnoid hemorrhage: a randomized controlled trial
Date of first enrolment:	2014/07/29
Target sample size:	450
Recruitment status:	Recruiting
URL:	https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000017082
Study type:	Interventional
Study design:	Parallel Randomized
Phase:	Not selected

Countries of recruitment

Japan

Contacts

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Affiliation:	National Defense Medical College Department of Neurosurgery	**Affiliation:**	National Defense Medical College Department of Neurosurgery

Key inclusion & exclusion criteria

Inclusion criteria:
Exclusion criteria: (1) severe brain edema
(2) heart dysfunction (New York Heart Association Class III or IV)
(3) renal insufficiency (calculated creatinine clearance rate of less than 30 mL/min), Fisher grade 4 with massive intracerebral hematoma, and rejection of randomization.

Age minimum: 20years-old
Age maximum: 80years-old
Gender: Male and Female

Health Condition(s) or Problem(s) studied

subarachnoid hemorrhage

Intervention(s)

intravenous hydrogen-rich fluid infusion with intra-cisternal magnesium sulfate infusion
intra-cisternal magnesium sulfate infusion only
placebo (control group)

Primary Outcome(s)

(1) Occurrence of delayed cerebral ischemia
(2) Occurrence of cerebral vasospasm

Secondary Outcome(s)

(1) Modified Rankin scale score at 3, 6, and 12 months
(2) Biochemical markers (malondialdehyde, neuron-specific enolase, S-100 calcium binding protein B, and C-reactive protein)

Secondary ID(s)

Source(s) of Monetary Support

Department of Neurosurgery, National Defense Medical College

Secondary Sponsor(s)

Ethics review

Status: YES
Approval date:
Contact:

Results

Results available:	
Date Posted:	
Date Completed:	
URL:	