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-UMIN000005752
Date of registration:	02/06/2011
Prospective Registration:	No
Primary sponsor:	Department of Neurosurgery, National Defense Medical College
Public title:	Molecular hydrogen for ischemic stroke
Scientific title:	Molecular hydrogen for ischemic stroke - Hydrogen for cerebral ischemia
Date of first enrolment:	2011/06/01
Target sample size:	20
Recruitment status:	Recruiting
URL:	https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000006749
Study type:	Interventional
Study design:	Single arm Non-randomized
Phase:	Not selected

Countries of recruitment

Japan

Contacts

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Affiliation:	National Defense Medical College (NDMC) Department of Neurosurgery	**Affiliation:**	National Defense Medical College (NDMC) Department of Neurosurgery

Key inclusion & exclusion criteria

Inclusion criteria:
Exclusion criteria: Patients with acute ischemic stroke beyond 24 hours of symptom onset.

Age minimum: 18years-old
Age maximum: 120years-old
Gender: Male and Female

Health Condition(s) or Problem(s) studied

Cerebral infarction

Intervention(s)

Intravenous drip infusion of hydrogen-rich saline

Primary Outcome(s)

modified Rankin scale (mRS) (days 7, 30, and 90), the NIHSS (days 7 and 90), and the Barthel Index (days 7, 30, and 90)

Secondary Outcome(s)

Safety Assessments
Vital signs were recorded at enrollment and at specified times throughout the infusion and follow-up periods. Routine laboratory data and ECGs were performed at the time of enrollment, at 24 and 72 hours, and on day 7 and were analyzed centrally (ECGs at day 7 were performed only if abnormal at 72 hours). To assess any effect of hydrogen on hemorrhagic transformation after alteplase administration, brain imaging was repeated after 72 hours in patients who were receiving concomitant treatment with alteplase. Symptomatic hemorrhagic transformation was defined as an increase in the NIHSS score of at least 4 points within 36 hours, plus evidence of any blood on neuroimaging after treatment with alteplase. Patients meeting criteria for progressive stroke (NIHSS increase of 4 points within 72 hours) or new stroke in the first week were also reimaged.

Secondary ID(s)

Source(s) of Monetary Support

MiZ Co., Ltd. CEO Fumitake Satoh 16-5, Zengyo 1-chome, Fujisawa-shi, Kanagawa-ken, 251-0871 Japan

None

Secondary Sponsor(s)

Ken-o-Tokorozawa Hospital Tokorozawa Central Hospital Self-Defense Forces Central Hospital Kuki General Hospital Nishijima Hospital

Ethics review

Status: YES
Approval date:
Contact:

Results

Results available:	
Date Posted:	
Date Completed:	01/06/2013
URL:	