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Effects of imatinib on cerebral vasospasm and prognosis of patients with aneurysmal subarachnoid haemorrhage

Submission date	Recruitment status	[ ] Prospectively registered
05/06/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/12/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/12/2011	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Effects of imatinib on cerebral vasospasm and Glasgow outcome score at 6 months in patients with aneurysmal subarachnoid haemorrhage: a prospective randomised controlled trial

Study objectives
Imatinib ameliorated cerebral vasospasm and improved Glasgow outcome score (GOS) at 6 months in subarachnoid haemorrhage (SAH) patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee,The First Affiliated Hospital of Harbin Medical University, China approved on 15th May 2011, Ref No.2011-18

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Aneurysmal subarachnoid haemorrhage

Interventions
1. Imatinib (400mg/d) (Glivec®) treatment within 72h after SAH and lasted for 7 days
2. Placebo control treatment and lasted for 7 days
At 3 and 6 month, the patients were followed up

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Imatinib

Primary outcome(s)
1. Mortality during hospital
2. Cerebral vasospasm evaluted by Doppler on day 7 after SAH
3. Brain oedema evaluted by magnetic resonance imaging (MRI) on day 7 after SAH

Key secondary outcome(s))
1. Dead
2. Vegetative state: Unable to interact with environment; unresponsive
3. Severe disability : Able to follow commands / unable to live independently
4. Moderate disability: Able to live independently; unable to return to work or school

5. Good recovery: Able to return to work or school
6. Glasgow outcome score at 6 month follow up

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Written informed consent signed by parents and/or legal guardian
2. Male or female, aged 18 - 80 years
3. Aneurysm treated by surgical clipping
4. Aneurysmal subarachnoid haemorrhage within 72 hours
5. Absence of major systemic illnesses (e.g. cancer, diabetes, renal failure or heart failure) as assessed by the medical doctor, upon initial clinical assessment
6. No known or reported history of chronical illness as cancer, diabetes, chronic heart, liver or renal disease
7. No pregnancy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. No written informed consent by parents/legal guardian and child
2. History of acute or severe chronic disease.(cancer, diabetes, chronic heart, liver or renal disease)
3. Participating in other clinical trials during the study
4. Pregnancy
5. Aneurysm treated by interventional coiling

Date of first enrolment
15/06/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
China

Study participating centre
No.23, Youzheng Street
Harbin
China
150001

Sponsor information

Organisation
The First Affiliated Hospital of Harbin Medical University (China)

ROR
https://ror.org/05vy2sc54

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (China)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration