

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

Submission date 05/06/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/12/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/12/2011	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please contact gaocheng8921@gmail.com or doctorgaocheng@yahoo.com.cn to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

15/06/2011

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 chronic illness as cancer, diabetes, chronic heart, liver or renal disease
7. No pregnancy

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

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)

Sponsor details

Heilongjiang

Harbin

China

150001

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/05vy2sc54>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (China)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration