

Safety and Efficacy of Low-dose Heparin during Intracranial Angioplasty and Stent placement: a randomized, double-blind, controlled study of 2000 IU versus 3000 IU bolus heparin

Submission date 29/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/05/2019	Condition category Surgery	<input type="checkbox"/> Individual participant data

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

Study information

Scientific Title

Safety and Efficacy of Low-dose Heparin during Intracranial Angioplasty and Stent placement: a randomized, double-blind, controlled study of 2000 IU versus 3000 IU bolus heparin

Acronym

SELHIAS

Study objectives

H0: low-dose heparin (2000 IU) group has more thromboembolus complications and similar intracranial bleeding complications compared with standard-dose of heparin (3000 IU) group during intracranial angioplasty and stent placement.

H1: low-dose heparin (2000 IU) group has fewer intracranial bleeding complications and similar thromboembolus complications compared with standard-dose of heparin (3000 IU) group during intracranial angioplasty and stent placement.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Intracranial angioplasty

Interventions

Stent-assisted angioplasty of the offending intracranial stenosis

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Heparin

Primary outcome measure

1. Efficacy end point was thromboembolus complications within 24h.
2. Safety end point was intracranial bleeding complications within 24h.

Secondary outcome measures

1. Intraoperative activated clotting time monitoring
2. Puncture site complications

Overall study start date

01/02/2005

Completion date

01/02/2006

Eligibility

Key inclusion criteria

1. 18-75 years of age
2. Recurrent ischemic events (transient ischemic attack and/or stroke) attributed to an intracranial stenosis $\geq 50\%$ at digital subtraction angiography (DSA)
3. Performed intracranial angioplasty and stent placement

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Not Specified

Target number of participants

60

Total final enrolment

64

Key exclusion criteria

1. Intracranial hemorrhage and major ischemic stroke (NIHSS ≥ 8) in the same hemisphere as the target lesion within 6 weeks
2. Concurrent severe extracranial artery stenosis and angioplasty and stent placement needed to be performed
3. Concurrent intracranial tumors, cerebral AVM and aneurysms
4. History of heparin allergy
5. Received perioperative heparin or surgical procedures requiring systemic heparinization
6. Preoperative platelet or coagulation abnormalities
7. Patients were not eligible if they could not cooperate with the study procedures or provide informed consent

Date of first enrolment

01/02/2005

Date of final enrolment

01/02/2006

Locations**Countries of recruitment**

China

Study participating centre

No. 6 Tiantan Xili

Beijing

China

100050

Sponsor information**Organisation**

The Ministry of Health of the People's Republic of China

Sponsor details

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Sponsor type

Government

ROR

<https://ror.org/01mv9t934>

Funder(s)

Funder type

Government

Funder Name

The Ministry of Health of The People's Republic of 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2009	23/05/2019	Yes	No