ISRCTN48605341 https://doi.org/10.1186/ISRCTN48605341

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

Registration date
14/09/2005

Overall study status
Completed

Last Edited
23/05/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jiang Wei-Jian

Contact details
No. 6 Tiantan Xili
Beijing
China
100050
+86 1067050137
cjr.jiangweijian@vip.163.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2004BA714B-7

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 ≥ 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
No.1 The South Road of Xizhimenwai
Beijing
China
100044
-
manluzhu@yahoo.com.cn

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