Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of surgical clipping and interventional coiling in the progressive anterior circulation aneurysms of brain.

Protocol summary

Study aim

The aim of this study was to comparison of surgical clipping and international coiling in the progressive anterior circulation of brain aneurysms.

Design

Randomized, community-based, and pragmatic clinical trial with parallel, double-blind, and randomized groups.

Settings and conduct

In this study, 120 patients who have been diagnosed with cerebral arterial aneurysm (GCS greater than or equal to 9) were investigated at Imam Reza Hospital and Shams Tabriz Hospital for the purpose of clipping surgery and coiling treatment interventions. Assignment of patients to intervention groups was done randomly using paired and randomized random numbers and patient records. At the end of the study, patients followed for post-operative mortality rate, post-surgical complications and re-bleeding and wall aneurysm improvement.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Glasgow coma scale (GCS) equal to and greater than 9, non-giant aneurysms of less than 10 mm in size, anterior cerebellar aneurysms. Exclusion criteria include: GCS less than 8, Giant's aneurysms greater than 10 mm, desiccant aneurysms.

Intervention groups

Intervention group 1 (Clipping): that the clips used to attach the neck of the brain's aneurysms. Intervention group 2 (Coiling): Using composite springs to fill the aneurysm and remove it from the main circulation system.

Main outcome variables

Post-operative mortality rate and complications, re-bleeding frequency and aneurysm wall improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120527009878N4**
Registration date: **2018-11-03, 1397/08/12**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-03, 1397/08/12**
Update count: **0**

Registration date

2018-11-03, 1397/08/12

Registrant information

Name

Firooz Salehpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3334 0830

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salehpourf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-11, 1397/05/20

Expected recruitment end date

2019-01-10, 1397/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of surgical clipping and interventional coiling in the progressive anterior circulation aneurysms of brain.

Public title

Comparison of surgical methods in the treatment of cerebral arteries aneurysms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Glasgow coma scale (GCS) equal or greater than 9 Non-giant aneurysms of less than 10 mm in size Anterior circular aneurysms of the brain

Exclusion criteria:

Glasgow coma scale (GCS) less than 8 Giant's aneurysms larger than 10 mm Desiccant aneurysms

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

First, patients will be listed by file number. Then, by using the rand command in Microsoft EXCEL 2007 software, for each patients, a code between 1 and 120 will be assigned. To divide the patients into the first and second intervention groups, using the code given to the patients, the patients with the odd code will be assigned to the first intervention group and the patients with the even code will be assigned into the second intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, clinical caregivers (operating room personnel), outcome elevators (operating room and neurosurgery ward nurses), and data analyzers will be blind to the profile of patients. Blindness will be done by removing the name and surname and other information that will allow access to patient profiles. Patients will be encoded, and this coding is obvious just to the researcher.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Central Building No. 2, Tabriz University of Medical Sciences, Golghast St

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2018-08-06, 1397/05/15

Ethics committee reference number

IR. TBZMED. REC. 1397. 389

Health conditions studied

1

Description of health condition studied

Cerebral anterior circular aneurysm

ICD-10 code

I67.1

ICD-10 code description

Cerebral aneurysm, nonruptured

Primary outcomes

1

Description

Post-operative mortality rate

Timepoint

Two weeks after intervention

Method of measurement

Questionnaire on postoperative complications

Secondary outcomes

1

Description

Post-surgical complications frequency

Timepoint

Intervention day, Four weeks after intervention

Method of measurement

Questionnaire on postoperative complications

2

Description

Re-bleeding frequency

Timepoint

Intervention day, Four weeks after intervention

Method of measurement

Questionnaire on postoperative complications

3

Description
Aneurysm wall improvement frequency
Timepoint
Intervention day, Four weeks after intervention
Method of measurement
Questionnaire on postoperative complications

Intervention groups

1

Description
Intervention group 1: In coiling intervention, composite springs are used to fill the aneurysm and remove it from the main circulation system. In this method, the neurosurgeon initially slices in the arterial arm or leg of the patient, and then sends the catheter to the brain and to the vascular aneurysm. The neurosurgeon then inserts a soft wire spring into the vascular aneurysm. This spring corrects blood flow and forms a blood clot that acts as a vascular aneurysm cushion and prevents it from bursting.
Category
Treatment - Surgery

2

Description
Intervention group 2: In this method, coiling is done with clipping. Composite springs are used to fill the aneurysm and remove it from the main circulation system. In this method, the neurosurgeon initially slices in the arterial arm or leg of the patient, and then sends the catheter to the brain and to the vascular aneurysm. The neurosurgeon then inserts a soft wire spring into the vascular aneurysm. This spring corrects blood flow and forms a blood clot that acts as a vascular aneurysm cushion and prevents it from bursting. Clips are then used to restrict the artery wall to perform Clipping.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurosurgery Ward of Emem Reza hospital
Full name of responsible person
Ramin Tutakhaneh Bonab
Street address
Emam Reza Hospital, Daneshgah Ave, Pishghadam
City
Tabriz
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5166614756
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ghaffar Shokuhi Tabrizi
Street address
Vice Chancellor for Research, Faculty of Medicine, Gholghasht Street, Azadi Street, Tabriz
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shokuhi.gh@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Firoz Salehpoor
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
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Neurosurgery ward, Emam Reza Hospital, Gholghasht Street, Azadi Street, Tabriz

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Person responsible for scientific inquiries

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Person responsible for updating data

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5166614756
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Fax
Email
salehpourf@tbzmed.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
A portion of the data that represents the final outcome
When the data will become available and for how long
Available after publication.
To whom data/document is available
All Physicians and residents of the neurosurgery department
Under which criteria data/document could be used
After obtaining permission from the neurosurgery department
From where data/document is obtainable
Person who responsible for scientific accountability of study.
What processes are involved for a request to access data/document
After approval of the research vice-president.
Comments