

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the Safety and Efficacy of Cerebral Angiography via Transradial Cerebral Angiography (TRA) and Transfemoral Cerebral Angiography (TFA): A Randomized Clinical Trial

Protocol summary

Study aim

Evaluation of the Safety and Efficacy of Cerebral Angiography via Transradial Cerebral Angiography (TRA) and Transfemoral Cerebral Angiography (TFA)

Design

A Randomized, Single-Blind, Parallel-Group Clinical Trial with a Concealed Randomization Sequence, Including 245 Patients. Block Randomization was performed using the Sealed Envelope website, and Allocation Concealment was ensured through Sealed Envelopes.

Settings and conduct

Cerebral Angiography Patients in Qaem and Razavi Hospitals were Randomly assigned to Intervention or Control using Block Randomization with Sealed Envelopes Data, Baseline Info and Angiography Results, were Analyzed

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Individuals with Various Cerebrovascular Diseases in Mashhad who have been Referred for Cerebral Angiography. Age above 18 Years. Exclusion Criteria: Heart Failure. Renal Failure. Patients with Non-Palpable Radial, Femoral, or Pedal Arteries. Patients with Inaccessible Radial or Femoral Arteries or Anatomical Abnormalities that Prevent Angiography. Patients with Hypersensitivity to Contrast Agents or Other Materials Used in the Angiography Procedure. Pregnant or Breastfeeding Women for whom Angiography may pose Risks to the Fetus or Infant.

Intervention groups

Transradial Group: Patients underwent Cerebral Angiography using the Transradial Approach (via the Radial Artery). A Catheter was inserted through the Radial Artery and guided toward the Cerebral Arteries. Transfemoral Group: Patients underwent Cerebral Angiography using the Transfemoral Approach (via the Femoral Artery). A Catheter was inserted through the Femoral Artery and guided toward the Cerebral Arteries.

Main outcome variables

Primary Outcome Variables include Intraoperative and Postoperative Complications, Technical Success, and Patient Comfort in Both Angiography Methods.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241223064139N1**

Registration date: **2025-02-06, 1403/11/18**

Registration timing: **retrospective**

Last update: **2025-02-06, 1403/11/18**

Update count: **0**

Registration date

2025-02-06, 1403/11/18

Registrant information

Name

Humain Baharvahdath

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-18, 1402/01/29

Expected recruitment end date

2024-04-17, 1403/01/29

Actual recruitment start date

2023-04-18, 1402/01/29
Actual recruitment end date
2024-04-17, 1403/01/29
Trial completion date
2024-04-17, 1403/01/29

Scientific title
Evaluation of the Safety and Efficacy of Cerebral Angiography via Transradial Cerebral Angiography (TRA) and Transfemoral Cerebral Angiography (TFA): A Randomized Clinical Trial

Public title
Evaluation of Cerebral Angiography via Transradial Cerebral Angiography (TRA) and Transfemoral Cerebral Angiography (TFA)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with Various Cerebral Disorders in Mashhad Who Underwent Cerebral Angiography Age more than 18 Years Old
Exclusion criteria:
Cardiac Failure Renal Failure Patients with Non-Palpable Radial, Femoral, or Pedal Arteries Patients with Inaccessible Radial or Femoral Arteries or Anatomical Abnormalities that Prevent Angiography Patients with Hypersensitivity to Contrast Agents or Other Materials Used in the Angiography Procedure Pregnant or Breastfeeding Women for whom Angiography may pose Risks to the Fetus or Infant

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **245**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization was employed as a reliable method to ensure balanced allocation of participants across treatment groups at the end of each block. To generate variable-sized random blocks, the online tool available at <https://www.sealedenvelope.com/simple-randomiser/v1/lits> was used. The tool's output provided a specific number of blocks with varying sizes (4 and 6) and different sequences of block contents, based on the sample size and the suggested block sizes. Subsequently, the contents of each block were concealed in sealed envelopes (allocation concealment), and upon patient enrollment, one of the blocks was randomly selected. The participant was then assigned to a study

arm according to the sequence specified within the block. Following the completion of the first block, the next block was randomly selected, and this process continued until the final block was exhausted and the last participant was allocated. Consequently, with the assignment of the final entry in the last block, participants were evenly distributed between the two study arms. To maintain impartiality, this procedure was carried out by an individual independent of the treatment team.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study employed single-blind masking, meaning that the patient remained unaware of the procedure type (transradial or transfemoral) to minimize subjective bias in outcome perception. To achieve this, the preparation, local anesthesia, and angiography procedures were conducted under appropriate coverage, ensuring that the patient does not receive any information regarding the access route. However, the treatment team (physicians and nurses) was aware of the procedure type, as this knowledge was essential for proper protocol implementation. To enhance accuracy, data analysis was performed by an individual or team blinded to group allocation (blinding in analysis or double-dummy). This approach minimized bias in result interpretation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2023-04-18, 1402/01/29

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.165

Health conditions studied

1

Description of health condition studied

Common Cerebrovascular Diseases including Aneurysm, Arterial Stenosis or Occlusion, Vasculitis, Spasm, and Vascular Malformations or Fistula (Arteriovenous Malformation or Arteriovenous fistula)

ICD-10 code

B31RZZZ

ICD-10 code description

Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes

1

Description

The Prevalence of Sheath Placement Success in Angiography

Timepoint

After Intervention

Method of measurement

Fluoroscopy (Sheath Placement Success Rate)

Secondary outcomes

1

Description

Radiation Dose

Timepoint

After Intervention

Method of measurement

Measurement Method: Using a fluoroscopy device that records the radiation dose absorbed by the patient. Unit: Milligray (mGy) or Entrance Skin Dose (ESD) in milligray and Dose-Area Product (DAP) in milligray per square centimeter (mGy·cm²).

2

Description

Surgery Time

Timepoint

After Intervention

Method of measurement

Time in Hour

3

Description

Fluoroscopy Time

Timepoint

After Intervention

Method of measurement

Time in Hour

4

Description

Degree of Disability/Dependence After The Stroke

Timepoint

After Intervention

Method of measurement

The Modified Rankin Scale (mRS)

5

Description

Patient Satisfaction

Timepoint

After Intervention

Method of measurement

Checklist Including Pain, Hematoma, Bruising, Edema, Discomfort, and Overall Satisfaction.

Intervention groups

1

Description

Intervention1: Transradial Group:In This Group, Patients Undergo Cerebral Angiography Using The Transradial Approach (Access Via The Radial Artery In The Wrist). In This Method, A Catheter Is Inserted Through The Radial Artery And Guided Toward The Cerebral Arteries.

Category

Treatment - Surgery

2

Description

Intervention 2: Transfemoral Group:In This Group, Patients Undergo Cerebral Angiography Using The Transfemoral Approach (Access Via The Femoral Artery In The Groin Region). In This Method, A Catheter Is Inserted Through The Femoral Artery And Guided Toward The Cerebral Arteries.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem hospital

Full name of responsible person

Humain Baharvahdat

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Qaem hospital, Shariati Square, Ahmadabad Blv

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Humain Baharvahdat

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Humain Baharvahdat

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In this study, the safety and efficacy of cerebral angiography using transradial and transfemoral access were compared and evaluated in patients. The collected data include demographic characteristics, clinical outcomes, access success rate, and potential adverse events. The documentation includes proposal forms, ethics approval, informed consent forms, raw data, statistical analysis tables (in SPSS format), and charts related to study results. Relevant information will be available upon request to qualified collaborators, subject to approval, via email (baharvahdath@mums.ac.ir).

When the data will become available and for how long

The data and documentation of this study will be available for public access for five years after the final results are published in a reputable scientific journal.

To whom data/document is available

Access to the data and documentation of this study will

be available to researchers, university faculty, and others interested in scientific research related to the study topic. Requests for access must include a detailed explanation of the research purpose and approval from the relevant institution.

Under which criteria data/document could be used

The data and documentation of this study may only be used for scientific research, statistical analyses, and knowledge advancement in the field of cerebral angiography. Use of these data is subject to compliance with research ethics guidelines, approval from the primary authors, and proper citation of the published article.

From where data/document is obtainable

To request access to the data and documentation of this study, please contact the corresponding author, Dr. Humain Baharvahdat, via his official email (baharvahdath@mums.ac.ir).

What processes are involved for a request to access data/document

1. The applicant must submit an official request to the corresponding author, including a detailed explanation of the research purpose, intended data usage, and approval from the relevant institution. 2. The request will be reviewed and approved if it aligns with scientific objectives and adheres to research ethics guidelines. 3. Upon approval, the applicant must sign a commitment to comply with data usage regulations and properly cite the published article. 4. Once the process is completed, the data and documentation will be provided to the applicant through a secure platform.

Comments