

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Impact of hypothermia on final outcome of patients with acute stroke: a randomized clinical trial

#### Protocol summary

##### Study aim

The effect of hypothermia on the final outcome of patients with acute stroke

##### Design

One-Blind randomized clinical trial with control group. Sampling was done by cluster random sampling and then divided into control and experimental groups by random method.

##### Settings and conduct

The population of the study included all patients with acute stroke in Hamadan province. After selecting the samples and dividing them into control and experimental groups, the intervention will be performed for 3 hours on the patients in the experimental group and the results of the two groups will be compared. Blinding is done by preventing the samples from being informed of their group type.

##### Participants/Inclusion and exclusion criteria

1. Having a hemorrhagic or ischemic stroke
2. Age over 18 years old
3. Informed consent form signed by the patient or his/her representative
4. Not having severe heart failure - Grade 2 and 3 based on cardiologist diagnosis
5. Absence of pulmonary embolism or acute myocardial infarction
6. Absence of any cardiac arrhythmia or ventricular or atrioventricular block in the ECG
7. Absence of acute or chronic sinusitis or current skull bone fracture
8. Not getting septicemia or bacteremia or severe blood infection at the admission time
9. Not having fever above 38.5 ° C when admitted
10. Absence of known blood diseases with increase the risk of thrombosis such as cryoglobulinemia, cold agglutination, or sickle cell anemia
11. Absence of known spastic venous complications, such as Raynaud's disease, or thromboangiitis obliterans
12. Weight less than 120 kg

##### Intervention groups

Hypothermia is performed by the cooling device on the patients in the intervention group, but for the control group only routine treatment is performed.

#### Main outcome variables

FOUR Score; APACHE score; NIHSS score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181105041565N1**

Registration date: **2019-04-23, 1398/02/03**

Registration timing: **retrospective**

Last update: **2019-04-23, 1398/02/03**

Update count: **0**

##### Registration date

2019-04-23, 1398/02/03

##### Registrant information

##### Name

abbas روزبهانی

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3225 5678

##### Email address

a.rozbahani@iaurmia.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-01, 1397/04/10

##### Expected recruitment end date

2018-12-31, 1397/10/10

##### Actual recruitment start date

2018-07-01, 1397/04/10

##### Actual recruitment end date

2018-11-25, 1397/09/04

**Trial completion date**

2018-11-28, 1397/09/07

**Scientific title**

Impact of hypothermia on final outcome of patients with acute stroke: a randomized clinical trial

**Public title**

Impact of cooling on patients with acute stroke

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having a hemorrhagic or ischemic stroke Age over 18 years old Informed consent form signed by the patient or his/her representative Not having severe heart failure - Grade 2 and 3 based on cardiologist diagnosis Absence of pulmonary embolism or acute myocardial infarction Absence of any cardiac arrhythmia or ventricular or atrioventricular block in the ECG Absence of acute or chronic sinusitis or current skull bone fracture Not getting septicemia or bacteremia or severe blood infection at the admission time Not having fever above 38.5 ° C when admitted Absence of known blood diseases with increase the risk of thrombosis such as cryoglobulinemia, cold agglutination, or sickle cell anemia Absence of known spastic venous complications, such as Raynaud's disease, or thromboangiitis obliterans Weight less than 120 kg

**Exclusion criteria:**

Death in less than 24 hours after admission Patient or legal guardian requisition for leaving the study Incidence of unwanted side effects includes intolerance, seizure, shivering, or physician discretion Incidence of cardiac dysrhythmias

**Age**

From **18 years** old to **90 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **70**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Cluster random sampling method will be used for sampling. Thus, from among 12 hospitals in Hamadan province, clusters from the internal and ICU wards will be randomly selected and the number of samples will be selected based on the number of hospitalized patients. Then, by simple random sampling method using by random numbers software, the samples will be assigned to the control and experimental groups and finally the samples of the two groups will be homogenized in terms

of individual characteristics.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Hiding the allocation of patients to the control and test group Not knowing the executives and people involved in analyzing the data from the control and experimental groups

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

A study is a randomized controlled trial with control group. The intervention only is done on experimental group and the control group received routine treatment.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University, Urmia Branch

**Street address**

Islamic Azad University., Urmia branch .,Salmas Road .,Orumieh

**City**

Orumieh

**Province**

West Azarbaijan

**Postal code**

5716963896

**Approval date**

2018-10-15, 1397/07/23

**Ethics committee reference number**

IR.IAU.URMIA.REC.1397.12

**Health conditions studied****1****Description of health condition studied**

stroke

**ICD-10 code**

G46

**ICD-10 code description**

Vascular syndromes of brain in cerebrovascular diseases

**Primary outcomes****1****Description**

level of patient alertness

**Timepoint**

A 72-hour period

**Method of measurement**

FOUR Score Scale: A tool that measures patient's alertness and level of consciousness.

**2****Description**

Predict the patient's recovery rate

**Timepoint**

A 72-hour period

**Method of measurement**

APACHE Scale that is used to measure the prognosis and recovery rate of the patients in critical care unit.

**3****Description**

Health level of patients

**Timepoint**

A 72-hour period

**Method of measurement**

The NIHSS scale a tool is used to health level of patients with stroke.

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Group A, that hypothermia is performed through the cooling device (Helmets) which is placed on the patient's head.

**Category**

Treatment - Other

**2****Description**

Control group: Group B that patients receive routine care and no intervention is performed.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

The research environment in this research is ICU wards of Hospitals affiliated to Hamadan University

**Full name of responsible person**

Abbas Rozbahani

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Park Street, Islamic Azad University, Malayer Town

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mehdi Zavari

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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**

Islamic Azad University

**Proportion provided by this source**

50

**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**

Islamic Azad University

**Full name of responsible person**

Abbas Rozbahani

**Position**

Mentor  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
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## Person responsible for scientific inquiries

### Contact

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Islamic Azad University  
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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Not disclosing private information of participants

### 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

The data is analyzed in the form of the SPSS software file by the statistical consultant. Patients names are be anonymous and the identification code is used for them. This data is kept confidential and is released from unauthorized persons.

### When the data will become available and for how long

From April 2019

### To whom data/document is available

Authorized individuals from Hamedan University of Medical Sciences and Islamic Azad University of Urumieh

### Under which criteria data/document could be used

In order to develop research in the field of hypothermia

### From where data/document is obtainable

Data is provided to the research deputy of Islamic Azad University of Urumieh

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

Through an official application from the research deputy of Islamic Azad University of Urumieh

### Comments

Research on the field of hypothermia by other researchers