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 cryoglobulinemian, 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
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Name of organization / entity
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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 cryoglobulinemian, 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
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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