Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Determining the effectiveness of Remote Ischemic Postconditioning in the treatment of patients with ischemic stroke - Randomized Clinical trial

Protocol summary

Study aim

Determining the effectiveness of Remote Ischemic Postconditioning in the treatment of patients with ischemic stroke

Design

This study is a parallel triple-blind clinical trial on 160 patients with intervention and control group. Restricted randomization method will be used to allocate patients into intervention and control groups. The researcher has no information about the selection sequence of samples and the type of procedure performed which are done by the nurses and trained individuals.

Settings and conduct

Location: Poursina Hospital (Rasht, Iran). The patient, researcher, and evaluator are blinded and samples are randomly selected.

Participants/Inclusion and exclusion criteria

*Inclusion criteria: No dependence on care before the stroke and Modified Rankin Scale (MRS) <= 2; Presence of a CT SCAN or MRI indicating the occurrence of the stroke; National Institutes of Health Stroke Scale (NIHSS) between 5 and 15 at the beginning; Less than 24 hours interval between the occurrence of the stroke and the onset of Remote Ischemic Postconditioning (RIPC); Signed informed consent by patients or companions.
*Non inclusion criteria: cerebral diseases; Previous brain surgery, hemorrhagic stroke or ischemic stroke in the last 3 months; Pregnancy, Severe comorbidity; Peripheral vascular disease, severe liver disease, history of chronic lung disease, liver disease, kidney disease; doctor's order.

Intervention groups

Group A (intervention group: patients undergoing RIPC with sphygmomanometer inflated up to 180 mmHg 5 minutes for 5 cycles with a 3 minute rest between cycles, at the admission); Group B (control group: patients undergoing same procedure with uninflated cuff).

Main outcome variables

1. NIHSS (National Institutes of Health Stroke Scale); 2. MRS (Modified Rankin Scale); 3.Clinical outcome; 4. Hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211226053525N1**
Registration date: **2022-01-22, 1400/11/02**
Registration timing: **prospective**

Last update: **2022-01-22, 1400/11/02**
Update count: **0**

Registration date

2022-01-22, 1400/11/02

Registrant information

Name
Mozaffar Hosseininezhad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 3332 2444

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Determining the effectiveness of Remote Ischemic Postconditioning in the treatment of patients with ischemic stroke - Randomized Clinical trial

Public title
Determining the effectiveness of Remote Ischemic Postconditioning in the treatment of patients with ischemic stroke

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
No dependence on care before the stroke and MRS score <= 2 Presence of a CT SCAN or MRI indicating the occurrence of the stroke National Institutes of Health Stroke Scale (NIHSS) score between 5 and 15 at the beginning Less than 24 hours interval between the occurrence of the stroke and the onset of RIPC Signed informed consent by patients or companions

Exclusion criteria:
Cerebral diseases such as intracranial aneurysm, vascular malformation and dementia Previous brain surgery, hemorrhagic stroke or ischemic stroke in the last 3 months Pregnancy Severe comorbidity (incurable disease, advanced cancer with low life expectancy, renal and hepatic failure, rheumatic diseases) Peripheral vascular disease, severe liver disease, history of chronic lung disease, liver disease, kidney disease, doctor's order

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, restricted randomization method in the form of block randomization will be used to allocate patients into intervention and control groups. For this purpose, four blocks with a ratio of 1: 1 will be considered. Sequences are marked in sealed envelopes with the letters A (intervention group) and B (control group). We will consider the size of the blocks randomly with a size of 4 or 6 to prevent the latest allocation from being detected. In the randomization process, random allocation sequences are identified by a statistician, and student collaborator in the project will register participants and allocate them to interventions.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In order to blind the subjects (patients) in the control group, the sphygmomanometer will be placed around patients' arm uninflated. In order to blind the researcher, allocators determine the groups without prior information using the allocation concealment method. The project will be performed based on patients groups by nurses or trained individuals. Final evaluation will be done by evaluators and physicians. In this study, restricted randomization method in the form of block randomization will be used to allocate patients into intervention and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committees of Guilan University of Medical science

Street address
Guilan University of Medical science

City
Rasht

Province
Guilan

Postal code
4144666949

Approval date
2021-12-15, 1400/09/24

Ethics committee reference number
IR.GUMS.REC.1400.446

Health conditions studied

1

Description of health condition studied
Ischemic stroke

ICD-10 code
I67.8

ICD-10 code description
Other specified cerebrovascular diseases

Primary outcomes

1

Description
National Institutes of Health Stroke Scale (NIHSS)

Timepoint
On admission, at discharge and on day 90

Method of measurement
Calculation of score through questionnaire and based on patient examination

2

Description
Modified Rankin Scale (MRS)
Timepoint
On admission, at discharge and on day 90
Method of measurement
Calculation of score through based on patient examination and scale

3

Description
Clinical outcome
Timepoint
at discharge
Method of measurement
Based on patients' files

4

Description
Hospital stay
Timepoint
at discharge
Method of measurement
Based on patients' files

Secondary outcomes

1

Description
Blood sugar
Timepoint
On admission, at discharge and on day 90
Method of measurement
Based on patient test results

2

Description
Blood pressure
Timepoint
On admission, at discharge and on day 90
Method of measurement
based on examination

3

Description
blood indices: Cell blood count (CBC), Prothrombin time (PT), The international normalized ratio (INR), Partial Thromboplastin Time (PTT)
Timepoint
On admission, at discharge and on day 90
Method of measurement
Based on patient test results

4

Description
Creatine kinase total
Timepoint
On admission, at discharge and on day 90
Method of measurement
Based on patient test results

5

Description
Creatinine (Cr)
Timepoint
On admission, at discharge and on day 90
Method of measurement
Based on patient test results

6

Description
Liver enzymes: Aspartate aminotransferase (AST) , Alanine transaminase (ALT)
Timepoint
On admission, at discharge and on day 90
Method of measurement
Based on patient test results

Intervention groups

1

Description
Intervention group: Remote Ischemic Postconditioning (RIPC) procedure will be performed on the first day of hospitalization under the following protocol: Sphygmomanometer will be attached to the patient's healthy arm and will be remained under the pressure of 180 (or 30mmHg more than patient's systolic BP if SBP>=180) mmHg for 5 minutes (ischemic phase) , followed by 3 minutes of rest (reperfusion phase). This cycle will be performed 5 times. All patients (both intervention group and control group) will receive the routine treatment in stroke management. The time from the onset of the stroke to RIPC should be less than 24 hours, with a golden time of 6 hours. The performance comparison of the two groups will be measured by National Institutes of Health Stroke Scale (NIHSS) and Modified Rankin Scale (MRS) criteria on days 0, discharge and 90. For biochemical measurements, the patient's serum will be sent to the laboratory and measured using routine methods.
Category
Treatment - Other

2

Description
Control group: RIPC procedure will be performed on the first day of hospitalization under the following protocol: Sphygmomanometer will be attached uninflated to the patient's healthy arm for 5 minutes , followed by 3 minutes of rest. This cycle will be performed 5 times. All

patients (both intervention group and control group) will receive the routine treatment in stroke management. The time from the onset of the stroke to RIPC should be less than 24 hours, with a golden time of 6 hours. The performance comparison of the two groups will be measured by NIHSS and MRS criteria on days 0, discharge and 90. For biochemical measurements, the patient's serum will be sent to the laboratory and measured using routine methods.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina hospital
Full name of responsible person
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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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Dr. Mozafar hosseininezhad
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Associate Professor of Neurology. Department of Neurology, School of Medicine. Neuroscience Research
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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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