

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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)  $\leq 2$ ; 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)

##### Phone

+98 13 3332 2444

##### Email address

hosseininezhadm@gmail.com

##### 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  $\leq 2$  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 $\geq$ 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**

Dr. Mozafar hosseinezhad

**Street address**

Namjoo street

**City**

Rasht

**Province**

Guilan

**Postal code**

4193713194

**Phone**

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hosseinezhadm@gmail.com

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<https://poursina.gums.ac.ir/>

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

Rasht University of Medical Sciences

**Full name of responsible person**

Dr.Mohammadreza Naghipour

**Street address**

Deputy of Research and Technology, in front of 17 Shahrivar Hospital, Namjoo St

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Rasht

**Province**

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4193713191

**Phone**

+98 13 3333 6394

**Email**

research@gums.ac.ir

**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 hosseinezhad

**Position**

Associate Professor of Neurology. Department of Neurology, School of Medicine. Neuroscience Research

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurology

**Street address**

Namjoo Street

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Dr. Mozafar hosseinezhad

**Position**

Associate Professor of Neurology. Department of Neurology, School of Medicine. Neuroscience Research

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Dr. Mozafar hosseininezhad

**Position**

Associate Professor of Neurology. Department of Neurology, School of Medicine. Neuroscience Research

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurology

**Street address**

Namjoo street

**City**

Rasht

## 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