Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of RIPC (remote ischemic preconditioning) on Migraine headache in patients with migraine : a pilot study

Protocol summary

Study aim
Evaluation of the effect of RIPC (remote ischemic preconditioning) on Migraine headache in patients with migraine : a pilot study

Design
This study is a parallel, double-blind clinical trial study on 30 patients with interventional (RIPC group) and control group (RIPC like group). Sample allocation will be based on the limited randomization approach using block randomization.

Settings and conduct
Location: Neurology Clinic of Poursina Hospital, Rasht. The outcome and data analyzer are blind and the samples are randomly selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients have at least 5 headache attacks lasting 4–72 hours (without treatment or unsuccessful treatment) ,Age range 18 to 50, Both male and female Gender , The onset of migraines before menopause, Patient's ability to distinguish migraine headaches from other conditions, Ability to fill out a questionnaire, ,Signed informed consent. Exclusion criteria: Different types of underlying diseases, History of chronic diseases or kidney, liver, cardiovascular, renal, pulmonary diseases, Any malignancy, autoimmune diseases ,Diabetes mellitus. Convulsions. Menopause. Head and neck trauma. Existence of cognitive impairment. Botox injection in the last 6 months. Pregnancy and lactation. Severe hypertension greater than 160/90 mm / hg. Non-migraine headaches. Drug and alcohol dependency. History of off- pump surgery.

Intervention groups
Group A (intervention group: patients undergoing RIPC procedure); Group B (control group: patients undergoing RIPC-like procedure).

Main outcome variables
Headache severity, Migraine-induced disability change, Lactate, CGRP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210212050334N3**
Registration date: **2022-05-30, 1401/03/09**
Registration timing: **prospective**

Last update: **2022-05-30, 1401/03/09**
Update count: **0**

Registration date
2022-05-30, 1401/03/09

Registrant information

Name
Amaneh Mohammadi Roushandeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date
2022-07-22, 1401/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of RIPC (remote ischemic preconditioning) on Migraine headache in patients with migraine : a pilot study

Public title
Evaluation of the effect of RIPC (remote ischemic preconditioning) on Migraine headache
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient have at least 5 headache attacks lasting 4–72 hours (without treatment or unsuccessful treatment) Age range 18 to 50 years Both male and female Gender The onset of migraines before menopause Ability of Patient to distinguish migraine headaches from other conditions Ability to fill out questionnaire Signed informed consent
Exclusion criteria:
Presence of underlying diseases, history of chronic diseases or kidney, liver, cardiovascular, renal, pulmonary diseases, any malignancy, autoimmunity diseases, diabetes mellitus Convulsions Menopause Head and neck trauma Existence of asthenic damage Mental disorders and major depression according to DSM4 Botox injection in the last 6 months Pregnancy and lactation Severe hypertension greater than 160/90 mm / hg Non-migraine headaches such as tension headaches that occur more than 12 times a month and cervicogenic Drug and alcohol dependency during one year prior to the study Rheumatism Migraine with aura History of off - pump surgery
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
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 two student collaborators in the project will register participants and allocate them to interventions.
Blinding (investigator's opinion)
Double blinded
Blinding description
Factors that cause errors in clinical trial studies are: patient awareness, researcher and researcher evaluation of the type of treatment prescribed. In the present study, according to the type of intervention approach used, patients, nurses and physicians will be aware of the new treatment process and there is no way to not inform them. However, analysts and the assignment of ten samples to groups will be blind. Therefore, the present study is designed for double blinds.
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
Vice Chancellor of Research and Technology of Guilan University of Medical Sciences,Shahid Siadati St., Namjoo St.
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rasht
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Guilan
Postal code
4193713194
Approval date
2022-03-09, 1400/12/18
Ethics committee reference number
IR.GUMS.REC.1400.620

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43.711
ICD-10 code description
Chronic migraine without aura, Intractable, With status migraineurs

Primary outcomes

1

Description
Headache intensity
Timepoint
Each time after the migraine attack (day 0 -60)
Method of measurement

According to the VAS index

2

Description
Migraine-induced disability
Timepoint
Days 0 and 90
Method of measurement
According to the MIDAS index

3

Description
Time of migraine start
Timepoint
At the admission
Method of measurement
Asking from patients

4

Description
Blood CGRP level
Timepoint
Days 0and 60
Method of measurement
ELISA kit

5

Description
Blood lactate level
Timepoint
Days 0 and 60
Method of measurement
Blood test

Secondary outcomes

1

Description
Migraine-induced disability
Timepoint
Days 0 and 90
Method of measurement
According to the MIDAS index

Intervention groups

1

Description
Intervention group: The patient undergoes RIPC protocol 6 days/ week. sphygmomanometer will be fastened to the patient's arm and will be remained under the pressure of 200 mmHg for 5 minutes (ischemic phase) , followed by 5 minutes of rest (reperfusion phase). This cycle will be performed 3 times.
Category
Treatment - Other

2

Description
Control group: In the control group, RIPC operation is performed as a sham or pseudo-ischemia, and no pressure is applied on arm.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina hospital
Full name of responsible person
Amaneh Mohammadi Roushandeh
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Web page address
https://www.gums.ac.ir/research
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
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Person responsible for updating data

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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