

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 13 3333 1520

Email address

mohammadi_roushandeh@gums.ac.ir

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.

City

rasht

Province

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 0 and 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

Street address

Poursina hospital, Parastar street, Rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4144666949

Phone

+98 13 3333 5820

Fax

+98 13 3333 6395

Email

mohammadi_roushandeh@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

City

Rasht

Province

Guilan

Postal code

4144666949

Phone

+98 13 3333 5820

Fax

+98 13 3333 6395

Email

research@gums.ac.ir

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

Amaneh Mohammadi Roushandeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

Street address

Anatomical Sciences department, Medicine faculty,
Guilan University of Medical Sciences, rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4144666949

Phone

+98 13 3333 5820

Fax

+98 13 3336 8540

Email

mohammadi_roushandeh@gums.ac.ir

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

Rasht University of Medical Sciences

Full name of responsible person

Amaneh Mohammadi Roushandeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

Street address

Anatomical Sciences department, Medicine faculty,
Guilan University of Medical Sciences, rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4144666949

Phone

+98 13 3333 5820

Fax

+98 13 3336 8540

Email

mohammadi_roushandeh@gums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Amaneh Mohammadi Roushandeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

Street address

Anatomical Sciences department, Medicine faculty,
Guilan University of Medical Sciences, rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4144666949

Phone

+98 13 3333 5820

Fax

+98 13 3336 8540

Email

mohammadi_roushandeh@gums.ac.ir

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