Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of RIPC (remote ischemic preconditioning) on migrane headache and Brain metabolites in MRS (magnetic resonance spectroscopy) and qEEG indices of migraine patients a pilot study

Protocol summary

Study aim

Evaluation of the effect of RIPC (remote ischemic preconditioning) on migrane headache and Brain metabolites in MRS (magnetic resonance spectroscopy) and qEEG indices of migraine patients a pilot study

Design

This study is a parallel double-blind clinical trial on 30 patients with intervention(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 assessor and data analyzer are blinded and 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, Gender of male and female, The onset of migraines before menopause,Patient's ability to distinguish migraine headaches from other conditions,Ability to fill out a questionnaire,Patient consent to enter the study,Signed informed consent. Exclusion criteria: Types of risk factors, history of chronic diseases or kidney, liver, cardiovascular, renal, pulmonary diseases, any malignancy, autoimmunity,diabetes mellitus. Convulsions. Menopause. head and neck trauma.Existence of cognitive impairment. Botox injections in the last 6 months.Pregnancy and lactation. Severe hypertension greater than 160/90 mm / hg.Non-migraine headaches. Drug and alcohol dependence. History of off pump surgery.

Intervention groups

Group A (intervention group: patients undergoing procedure); Group B (control group: patients undergoing RIPC-like procedure as described in method).

Main outcome variables

Glutamate, choline, creatine, N-acetyl aspartate, myoinositol GABA Glutamate/Cr NAA/Cr myoinisitol/Cr Frequency bands, Coherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210212050334N4**
Registration date: **2022-06-17, 1401/03/27**
Registration timing: **prospective**

Last update: **2022-06-17, 1401/03/27**
Update count: **0**

Registration date

2022-06-17, 1401/03/27

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

2022-08-06, 1401/05/15

Expected recruitment end date

2023-03-20, 1401/12/29

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 migrane headache and Brain metabolites in MRS (magnetic resonance spectroscopy) and qEEG indices of migraine patients a pilot study

Public title

Evaluation of the effect of RIPC (remote ischemic preconditioning) on migrane headache and Brain metabolites in MRS (magnetic resonance spectroscopy) and qEEG indices of migraine patients a pilot study

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 from 18 to 50 years The onset of migraines before menopause The ability of patients to distinguish migraine headaches from other conditions The patient's ability to fill out questionnaire Both male and female gender Informed consent

Exclusion criteria:

Underlying diseases, history of chronic diseases or kidney, liver, cardiovascular, renal, pulmonary diseases, any malignancy, autoimmunity, diabetes mellitus Convulsions Menopause Head and neck trauma Asthenic damage Mental disorders and major depression according to DSM4 Botox injection in the last 6 months Pregnancy and lactation Non-migraine headaches such as tension headaches that occur more than 12 times a month and cervicogenic Drug and alcohol dependence during the 1 year prior to the study Migraine with aura History of off pump surgery Severe hypertension higher than 160/90 mm / hg Rheumatism

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. The "R" software will be used for randomization. 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 to prevent the latest allocation from being detected. In the randomization process, random allocation sequences are identified by a statistician, and one student collaborators in the project will register participants and allocate them to interventions.

Blinding (investigator's opinion)

Double blinded

Blinding description

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 and they are not blind. However,data analyzer and who assesses the patients outcomes are 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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4193713194

Approval date

2022-03-09, 1400/12/18

Ethics committee reference number

IR.GUMS.REC.1400.603

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 migrainosus

Primary outcomes

1

Description
Glutamate
Timepoint
Days 0 and 60
Method of measurement
Magnetic resonance spectroscopy (MRS) test

2

Description
N-acetyl aspartate
Timepoint
Days 0 and 60
Method of measurement
MRS test

3

Description
Choline
Timepoint
Days 0 and 60
Method of measurement
MRS test

4

Description
Creatine
Timepoint
Days 0 and 60
Method of measurement
MRS test

5

Description
Myoinositol
Timepoint
Days 0 and 60
Method of measurement
MRS test

6

Description
GABA
Timepoint
Days 0 and 60
Method of measurement
MRS test

7

Description
Glutamate/Creatine
Timepoint
Days 0 and 60
Method of measurement
Math

8

Description
NAA/Cr
Timepoint
Days 0and 60
Method of measurement
Math

9

Description
Choline/Cr
Timepoint
Days 0 and 60
Method of measurement
Math

10

Description
Myoinisitol/Cr
Timepoint
Days 0and 60
Method of measurement
Math

11

Description
Absolute frequency bands
Timepoint
Days 0 and 60
Method of measurement
Qeeg

12

Description
Relative frequency bands
Timepoint
days 0and 60
Method of measurement
Qeeg

13

Description
Coherence
Timepoint
Days 0 and 60
Method of measurement
Qeeg analyze

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: Intervention group: The patient undergoes RIPC protocol 6 days a week. sphygmomanometer will be attached 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, this operation is performed as a sham or pseudo-ischemia, no pressure is applied.

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

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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

Amaneh Mohammadi Roushandeh

Position

استادتمام

Latest degree

Ph.D.

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