

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Valsalva maneuver on migraine

Protocol summary

Study aim

Evaluating the effect of the Valsalva maneuver as a non-pharmacological method on reducing and control of migraine headaches.

Design

The double-blind randomized clinical trial, 62 patients in the intervention group and 62 patients in the control group, diagnoses migraine based on the ICHD3 criterion, randomized using Sealdenvelop.com.

Settings and conduct

The patients use the device in the acute phase of headache at home. Patients and researchers collecting the information and the person analyzing the data are unaware of classifying. The blinding is done for all of them.

Participants/Inclusion and exclusion criteria

The inclusion criterion is migraine headache and the exclusion criteria are contraindications of Valsalva maneuvers such as some heart, brain and eye diseases.

Intervention groups

To create the Valsalva maneuver, we have designed a device that is similar to the Valsalva maneuver. People exhale in this device, against a pressure of 40 mm Hg for 15 seconds and then normal breathing, experience all four phases of the Valsalva maneuver. The control group are given an inefficient device.

Main outcome variables

Migraine headaches, analgesic medicine consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210525051405N1**

Registration date: **2021-09-15, 1400/06/24**

Registration timing: **retrospective**

Last update: **2021-09-15, 1400/06/24**

Update count: **0**

Registration date

2021-09-15, 1400/06/24

Registrant information

Name

Kamran Shirbache

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-18, 1399/12/28

Actual recruitment start date

2020-09-22, 1399/07/01

Actual recruitment end date

2021-03-18, 1399/12/28

Trial completion date

2021-06-20, 1400/03/30

Scientific title

The effect of Valsalva maneuver on migraine

Public title

The effect of Valsalva maneuver on migraine

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Migraine patients who have been diagnosed with migraine for more than one year Patients less than 50 years old.

Exclusion criteria:

history of cerebrovascular aneurysm, history of recent

brain surgery (less than 6 months), history of hemorrhagic stroke history of recent myocardial infarction (less than 6 months), history of heart failure and coronary artery disease history of syncope Uncontrolled hypertension, Systolic blood pressure less than 90 mm Hg and above 140 mm Hg retinopathy, Recent history of retinal surgery (less than 6 months), Intraocular lens implantation, history of cough induced headache Uncontrolled diabetes Aortic valve stenosis, Carotid artery stenosis

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **124**

Actual sample size reached: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, among the patients referred to the neurology clinic, migraine patients entered the intervention or control group based on random blocked method. The website named "Sealdenvelop.com" is used for this purpose. This site randomly divides the patients into groups of 4. The intervention group is given code A and the control group is given code B, and the groups are formed like ABBA, ABAB, BABA, etc. The examiner puts the patients in the order of enrollment in groups of four, and accordingly, each person is randomly given the code of the intervention group (A) or the code of the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

patients in the study, are unaware of the classifying of the intervention or control group, and in explaining the use of the Valsalva maneuver simulator (true or false), they have been told that it might be effective on their headache. Therefore, they use it according to the instructions and mention its effect in the questionnaire. The Investigators who are in touch with the patients, track the use of devices, and gather information are unaware of the intervention and control group division; that is to say, they do not know coding A and B. The person who extracts the information and conducts the statistical analysis is unaware of the intervention and control group division and the meaning of coding.

Placebo

Used

Assignment

Parallel

Other design features

A false Valsalva maneuver simulator is given to the control group to remove the Placebo effect without putting pressure on the individual.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Neuroscience Institute

Street address

Fourth Floor, Iranian Center of Neurological Research Building, Imam Khomeini Hospital, Keshavarz Blvd, Tehran

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Approval date

2020-11-21, 1399/09/01

Ethics committee reference number

IR.TUMS.NI.REC.1399.043

Health conditions studied**1****Description of health condition studied**

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes**1****Description**

score of headache in the questionnaire

Timepoint

before and after Valsalva maneuver

Method of measurement

Questionnaire and individual statement

Secondary outcomes**1****Description**

Taking medicine

Timepoint

In acute and chronic phases of headache

Method of measurement

questionnaire and individual statement

2**Description**

quality of life

Timepoint

Before and during the trial

Method of measurement

Questionnaire

Intervention groups**1****Description**

Intervention group: To create the Valsalva maneuver, we have designed a device that is similar to the Valsalva maneuver. People exhale in this device, against a pressure of 40 mm Hg for 15 seconds and then normal breathing, experience all four phases of the Valsalva maneuver. They are asked to do this action in the acute phase headache for three times with five minutes intervals. They are also allowed to repeat this maneuver later in the chronic phase headache and register the data.

Category

Treatment - Devices

2**Description**

Control group: To counteract the placebo effect, people in this group are given a device similar to the intervention group, but in this device there is no pressure on the exhalation of people and they only do normal exhalation in this device, they do not experience any of the steps of Valsalva maneuver. . They are asked to perform this operation three times in the acute phase of the headache, five minutes apart. They are also allowed to repeat the maneuver later in the chronic phase of the headache and record the data.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sina hospital

Full name of responsible person

Mansoureh Togha

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2**Recruitment center****Name of recruitment center**

Doctor Mansoureh Togh's neurology clinic

Full name of responsible person

Mansoureh Togha

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Web page address**3****Recruitment center****Name of recruitment center**

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Full name of responsible person

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

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Tehran 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

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

Tehran University of Medical Sciences

Full name of responsible person

Mansoureh Togha

Position

Professor of Neurology

Latest degree

Specialist

Other areas of specialty/work

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

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Full name of responsible person

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Position

General practitioner

Latest degree

Medical doctor

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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

To protect patients' personal information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Only information on reducing the severity of headaches

and taking painkillers will be provided. Excel file of patients' information extracted from questionnaires will be provided.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

It is only available for people working in academic institutions.

Under which criteria data/document could be used

Request information will be available for further studies or meta-analysis.

From where data/document is obtainable

Through correspondence with the scientific supervisor of the project, Dr. Togha, or the project manager, Dr. Kamran Shirbacheh (toghae@sina.tums.ac.ir, k-shirbache@alumnus.tums.ac.ir)

What processes are involved for a request to access data/document

After correspondence and persuasion of the project owners, information will be sent to the applicant at the earliest opportunity.

Comments