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
Supportive

Inclusion/Exclusion 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.

**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**

<table>
<thead>
<tr>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethics committee</strong></td>
</tr>
<tr>
<td>Name of ethics committee</td>
</tr>
<tr>
<td>Research Ethics Committees of Neuroscience Institute</td>
</tr>
<tr>
<td><strong>Street address</strong></td>
</tr>
<tr>
<td>Fourth Floor, Iranian Center of Neurological Research Building, Imam Khomeini Hospital, Keshavarz Blvd, Tehran</td>
</tr>
<tr>
<td><strong>City</strong></td>
</tr>
<tr>
<td>Tehran</td>
</tr>
<tr>
<td><strong>Province</strong></td>
</tr>
<tr>
<td>Tehran</td>
</tr>
<tr>
<td><strong>Postal code</strong></td>
</tr>
<tr>
<td>1419733141</td>
</tr>
<tr>
<td><strong>Approval date</strong></td>
</tr>
<tr>
<td>2020-11-21, 1399/09/01</td>
</tr>
<tr>
<td><strong>Ethics committee reference number</strong></td>
</tr>
<tr>
<td>IR.TUMS.NI.REC.1399.043</td>
</tr>
</tbody>
</table>

**Health conditions studied**

<table>
<thead>
<tr>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description of health condition studied</strong></td>
</tr>
<tr>
<td>Migraine</td>
</tr>
<tr>
<td><strong>ICD-10 code</strong></td>
</tr>
<tr>
<td>G43</td>
</tr>
<tr>
<td><strong>ICD-10 code description</strong></td>
</tr>
<tr>
<td>Migraine</td>
</tr>
</tbody>
</table>

**Primary outcomes**

<table>
<thead>
<tr>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>score of headache in the questionnaire</td>
</tr>
<tr>
<td><strong>Timepoint</strong></td>
</tr>
<tr>
<td>before and after Valsalva maneuver</td>
</tr>
<tr>
<td><strong>Method of measurement</strong></td>
</tr>
<tr>
<td>Questionnaire and individual statement</td>
</tr>
</tbody>
</table>

**Secondary outcomes**

<table>
<thead>
<tr>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>Taking medicine</td>
</tr>
<tr>
<td><strong>Timepoint</strong></td>
</tr>
<tr>
<td>In acute and chronic phases of headache</td>
</tr>
</tbody>
</table>
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
Street address
Sina hospital, hassan abad square, Emam Khomeini street, Tehran
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 4561 7676
Fax
+98 21 6634 8553
Email
hosp_sina@sina.tums.ac.ir
Web page address
http://sinahospital.tums.ac.ir/

2
Recruitment center
Name of recruitment center
Doctor Mansoureh Togh's neurology clinic
Full name of responsible person
Mansoureh Togha
Street address
Unit 20, Floor 5, Iranian Doctors Building, Street No. 24, First Ghaem magham street, seventh of Tir square, Tehran
City
Tehran
Province
Tehran
Postal code
1586984447
Phone
+98 21 8832 8351
Email
Toghae@sina.tums.ac.ir
Web page address

3
Recruitment center
Name of recruitment center
Doctor Vahid Shaygan nejad's neurology clinic
Full name of responsible person
Vahid Shaygan Nejad
Street address
Unit 25, Third Floor, Hakim building, Ferdowsi St, Palestine Crossroads, Isfahan
City
Isfahan
Province
Isfahan
Postal code
8143995155
Phone
+98 31 3224 0626
Email
v.shaygannejad@gmail.com

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
The Iranian Center of Neurological Research
Full name of responsible person
Payam Sarraf

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

City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 2398
Fax
+98 21 6658 1558
Email
icnr@tums.ac.ir
Web page address
http://ni.tums.ac.ir/nd/en/

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

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Kamran Shirbache
Position
General practitioner

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
plate 3, alley 70, Bagh Daryache street, Isfahan

City
Isfahan
Province
Isfahan
Postal code
817674461
Phone
+98 31 3786 8449
Email
k-shirbache@alumnus.tums.ac.ir

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
Neurology

Street address
Unit 20, Floor 5, Iranian Doctors Building, Street No. 24, First Ghaem magham street, seventh of Tir square, Tehran

City
Tehran
Province
Tehran
Postal code
1586984447
Phone
+98 21 6694 0036
Fax
+98 21 6642 0556
Email
Toghae@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Kamran Shirbache
Position
General practitioner

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
plate 3, alley 70, Bagh Daryache street, Isfahan

City
Isfahan
Province
Isfahan
Postal code
817674461
Phone
+98 31 3786 8449
Email
k-shirbache@alumnus.tums.ac.ir
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