

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Evaluation of employing direct tactile pressure on the external carotid artery to relieve acute episode attack of migraine: An interventional study

#### Protocol summary

##### Study aim

Evaluation of the transient pressure effect on the middle part of external carotid artery for terminating an acute attack of migraine

##### Design

Interventional study without a control limb

##### Settings and conduct

Patients with migraine headache who come to urgent department and the intervention will be applied in this unit. Pain intensity was evaluated by Universal Pain Assessment Tools (UPAT). In safe position, applying vital signs monitoring and ipsilateral type of headache, a gentle pressure was applied on the carotid artery, lateral to the cricothyroid membrane and medial border of the Sterno- Cleido- Mastoid (SCM), by using both index and middle fingers, till the headache was relieved, following which the pressure was maintained for a period of 15 seconds. Then the middle finger was maintained at its position and the index finger slid caudally with the same pressure as far a distance of four centimeters and the pressure withdrawn slowly. After 2 minutes, patients were asked to report any change in headache which was recorded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients in range of 18 -45 years old, with established migraine based on International Classification of Headache Disorders (ICDH) guidelines, who had no atheromatous plaque in their carotid arteries. Exclusion criteria: Patients with histories of syncopal attacks, sensitivity of carotid sinus, cardiac dysrhythmia, neurologic disease, basilar migraine and patients with another non migraine headache symptoms

##### Intervention groups

Patients with migraine headache who come to urgent department. This study has not control group.

##### Main outcome variables

Reduction in pain intensity score.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150116020676N4**

Registration date: **2019-07-21, 1398/04/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-07-21, 1398/04/30**

Update count: **0**

##### Registration date

2019-07-21, 1398/04/30

##### Registrant information

##### Name

Farhad Tavakoli

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2226 9950

##### Email address

ftavakoli@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-21, 1398/04/30

##### Expected recruitment end date

2019-09-21, 1398/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of employing direct tactile pressure on the external carotid artery to relieve acute episode attack of migraine: An interventional study

### Public title

Effect of pressure on external carotid artery in treatment of acute migraine headache

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Established migraine, based on International Classification of Headache Disorders (ICDH) guidelines, in whom color doppler sonography of the carotid arteries depicted no narrowing of the carotid arteries or any atheromatous plaque.

#### Exclusion criteria:

Patients with histories of syncopal attacks Sensitivity of carotid sinus Cardiac dysrhythmia History of any neurologic disease Patients with another non migraine headache symptoms Basilar migraine

### Age

From **18 years** old to **45 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Central organization of Tehran of medical sciences, Ghods St. , keshavarz Blv.

##### City

Tehran

#### Province

Tehran

#### Postal code

1417653761

#### Approval date

2018-05-20, 1397/02/30

#### Ethics committee reference number

IR.TUMS.IKHC.REC.1397.182

## Health conditions studied

### 1

#### Description of health condition studied

Migraine headache

#### ICD-10 code

G43

#### ICD-10 code description

Migraine

## Primary outcomes

### 1

#### Description

Reduction in pain score evaluated by universal pain assessment tools (UPAT)

#### Timepoint

2 minutes after removing the pressure on carotid artery

#### Method of measurement

Universal Pain Assessment Tools

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In safe position, applying vital signs monitoring and ipsilateral type of headache, a gentle pressure was applied on the carotid artery, lateral to the cricothyroid membrane and medial border of the Sternocleidomastoid (SCM), by using both index and middle fingers, till the headache was relieved, following which the pressure was maintained for a period of 15 seconds. Then the middle finger was maintained at its position and the index finger slid caudally with the same pressure as far a distance of four centimeters and the pressure withdrawn slowly. After 2 minutes, patients were asked to report any change in headache which was recorded.

#### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Emergency Department, Imam Khomeini Hospital  
Complex

**Full name of responsible person**

Farhad Tavakoli

**Street address**

Imam Khomeini Hospital, Keshavariz Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

14197-33141

**Phone**

+98 21 6119 2828

**Email**

fahatv@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Shahin Akhond zadeh M.D

**Street address**

,Imam Khomeini Hospital, Keshavariz Blvd.

**City**

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**Province**

Tehran

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**Phone**

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**Email**

fahatv@yahoo.com

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

Yes

**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**

Farhad Tavakoli

**Position**

Pain fellowship

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Imam Khomeini Hospital, Keshavariz Blvd.

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data about the results will be accessible.

**When the data will become available and for how long**

Access to patients data will be available 6 months after publication

**To whom data/document is available**

Data and results from this study only available for scientific and academic centers.

**Under which criteria data/document could be used**

There is no limitation for accessible data analyzing.

**From where data/document is obtainable**

data request will be replied by this email address:  
fahatv@yahoo.com

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

After sending data request email, we will answer in 2 weeks.

**Comments**