

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of lidocaine injection in tender points of head in patients with chronic daily headaches

Protocol summary

Study aim

The effect of lidocaine injection in tender points of head in patients with chronic daily headaches

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Patients are examined for points of tenderness in the head and points of tenderness are identified in the patient. Then the patients in the intervention group were subcutaneously treated with topical injection of 1% lidocaine 2% in the areas of high tension. Patients in the control group were also given 1-2 cc normal saline. Patients are then reassessed one week, one month, two months and three months after the injection and the mean of headache severity and number of days of headache per week are assessed at each patient visit.

Participants/Inclusion and exclusion criteria

patients with chronic daily headaches

Intervention groups

patients with chronic daily headaches

Main outcome variables

Average daily headache severity; The number of days a week a patient has a headache; Average daily headache severity

General information

Reason for update

Correcting the code of ethics and changing the person responsible

Acronym

IRCT registration information

IRCT registration number: **IRCT20200305046704N1**

Registration date: **2020-03-11, 1398/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-27, 1399/06/06**

Update count: **1**

Registration date

2020-03-11, 1398/12/21

Registrant information

Name

maryam mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3012

Email address

mry.mohammadimd@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-10, 1398/12/20

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

2020-03-10, 1398/12/20

Actual recruitment end date

2020-03-19, 1398/12/29

Trial completion date

2020-06-18, 1399/03/29

Scientific title

The effect of lidocaine injection in tender points of head in patients with chronic daily headaches

Public title

The effect of lidocaine injection in tender points of head in patients with chronic daily headaches

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

chronic daily headache

Exclusion criteria:
Head injury history Head Surgery Brain tumors
depression and anxiety

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **64**
Actual sample size reached: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
By the method of randomized block

Blinding (investigator's opinion)
Double blinded

Blinding description
Researcher and participant with 4-block method

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of
Medical Sciences

Street address
Golestan Hospital, Farvardin Street

City
ahvaz

Province
Khouzestan

Postal code
6136753133

Approval date
2020-02-15, 1398/11/26

Ethics committee reference number
IR.AJUMS.REC.1398.890

Health conditions studied

1

Description of health condition studied

chronic daily headache

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Average daily headache severity

Timepoint

One week, one month, two months and three months
after injection

Method of measurement

HIT6 , VAS score

Secondary outcomes

1

Description

The number of days a week a patient has a headache

Timepoint

One week, one month, two months and three months
after injection

Method of measurement

Headache Impact Test Questionnaire(HIT6)

Intervention groups

1

Description

Intervention group: headache patients with tenderness
points

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Mryam mohammadi

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

محمد بدوی

Street address

Golestan highway

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1579461357

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Davood Kashipazha

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam mohammadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available	make this available
Study Protocol	Title and more details about the data/document
Undecided - It is not yet known if there will be a plan to make this available	All potential data can be shared after unidentifiable people
Statistical Analysis Plan	When the data will become available and for how long
Undecided - It is not yet known if there will be a plan to make this available	Start access period after printing results
Informed Consent Form	To whom data/document is available
Undecided - It is not yet known if there will be a plan to make this available	It will be available to researchers working in academic and scientific institutions
Clinical Study Report	Under which criteria data/document could be used
Undecided - It is not yet known if there will be a plan to make this available	Meta-analysis
Analytic Code	From where data/document is obtainable
Undecided - It is not yet known if there will be a plan to make this available	mry.mohammadimd@yahoo.com
Data Dictionary	What processes are involved for a request to access data/document
Undecided - It is not yet known if there will be a plan to	send mail
	Comments