

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Efficacy of greater occipital nerve block in postdural puncture headache

Protocol summary

Study aim

In this study we aimed to evaluate the efficacy of bilateral greater occipital nerve block in post dural puncture headache (PDPH).

Design

parallel groups, randomized, controlled trial on 28 patients, phase 3, enrolled between April 2019 to April 2020.

Settings and conduct

This randomized clinical trial is conducted at Tehran Shariati hospital in 2019-2020. 28 patients with diagnosis of PDPH based on HIS criteria enter the study in two groups. Patients are taken informed consent. Patients are categorized into two groups: the conservative treatment group (conservative treatment including hydration, bed rest and acetaminophene 1 gr/qds) and the occipital nerve block group. VAS (Visual Analogue Scale, a pain severity scale) is used to measure outcome in both groups 10 minutes, 2 hrs, 6 hrs, 12 hrs, 24 hrs and 48 hrs after intervention. Two groups are compared regarding VAS in different time points of study. Statistical analysis is performed with SPSS version 22.

Participants/Inclusion and exclusion criteria

Inclusion criteria consist of patients with post dural puncture headache due to IHS criteria. Exclusion criteria include history of greater occipital nerve injection within previous three months, hypersensitivity to the Lidocaine or Triamcinolone, seizure, local infection of the scalp, medication overuse headache, head surgery, severe hepatic failure, unstable vital signs, fever, chronic daily headache or thunderclap headache after dural puncture.

Intervention groups

Patients are categorized into two groups: the conservative treatment group (conservative treatment including hydration, bed rest and acetaminophene 1 gr/qds) and the occipital nerve block group.

Main outcome variables

VAS (Visual Analogue Scale) score in 10 min, 2 h, 12 h, 24 h, 48 h

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200621047860N1**

Registration date: **2020-08-06, 1399/05/16**

Registration timing: **retrospective**

Last update: **2020-08-06, 1399/05/16**

Update count: **0**

Registration date

2020-08-06, 1399/05/16

Registrant information

Name

Ghaemeh Nabaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2209 4369

Email address

nabaei.gh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2020-04-03, 1399/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of greater occipital nerve block in postdural

puncture headache

Public title

Efficacy of greater occipital nerve block in postdural puncture headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with post dural puncture headache based on IHS criteria

Exclusion criteria:

history of greater occipital nerve injection within previous three months hypersensitivity to the Lidocaine or Triamcinolone seizure local infection of the scalp medication overuse headache head surgery Severe hepatic failure unstable vital signs fever chronic daily headache thunderclap headache after dural puncture

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the method described in the article "Random sampling and allocation using SPSS" (DOI:10.5959/eimj.v4i1.4) and by using the software IBM SPSS statistics' random number generator tool, the patients were randomized into 2 groups. A block random allocation method (block size=4) with no stratum was implemented in this regard. There was no allocation concealment as the study was not blinded.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

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

No 1, Poursina St., Ghods St., Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2019-03-02, 1397/12/11

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.221

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

G44

ICD-10 code description

Other headache syndromes

Primary outcomes

1

Description

headache

Timepoint

10 min, 2h, 6h,12h, 24h, 48h after injection

Method of measurement

Visual analog scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A single bilateral greater occipital nerve block using 2% lidocaine, 2cc for each side and normal saline, 2.5cc for each side

Category

Treatment - Drugs

2

Description

Control group: Conservative treatment, including hydration, 1gr acetaminophen every 6 hours and resting.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Shariati hospital

Full name of responsible person

Siamak Abdi Dizaji

Street address

Jalal-e-Al-e-Ahmad Hwy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali sahraian

Street address

District 6, Keshavarz Boulevard and Ghods St. crossing

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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

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

Siamak Abdi Dizaji

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for updating data

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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

"There is no further information"

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available