Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 apin 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 sings, 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
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Iran (Islamic Republic of)
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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:
Paitents 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 sings 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

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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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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