Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Survey of the analgesic effect of venous Paracetamol in comparison with the combination of venous Paracetamol and Propofol in the relief of acute migraine headache

Protocol summary

Study aim
Determine the amount of pain in intravenous Paracetamol compared to Paracetamol and Propofol in the relief of acute migraine headache

Design
Two arm parallel group randomised trial with blinded postoperative care and blocking randomize method, with 80 patients.

Settings and conduct
This study will be conducted at Khatam al-Anbia hospital in Zahedan. Also, it's a double-blind type of study, which only the doctor responsible for distributing the medicine knows the name of drugs, and patient and the other physician who records the pain score are blinded.

Participants/Inclusion and exclusion criteria
The inclusion criteria are: Failure to receive narcotic drugs or other Triptans like vasoconstrictor, such as Dihydroergotamine, within 24 hours before referral to the emergency department; Patients treated with systemic Corticosteroids; Patients with Diabetes Mellitus history, active gastrointestinal ulcers, myocardial infarction in the last week; Family history of hypocalmic paralysis (for Dexamethasone). Exclusion criteria are those who have kidney failure.

Intervention groups
Intervention group 1: received 1000 mg paracetamol (A)
Intervention group 2: received 500 mg paracetamol and 0.5 mg per kilogram of perpofol (due to combination of paracetamol and propofol, paracetamol dose reduced to 500 mg) (B)

Main outcome variables
Pain score (VAS) will be evaluated from 0 to 10, so that zero equals the absence of pain and 10 equals to be the most conceivable pain for the patient.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180628040274N1**
Registration date: **2018-08-24, 1397/06/02**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-24, 1397/06/02**
Update count: **0**

Registration date
2018-08-24, 1397/06/02

Registrant information
Name
Farahnaz Ahmadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 54 3329 5744
Email address
farahnaz.ahmadi@zaums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-08-21, 1397/05/30
Expected recruitment end date
2019-02-18, 1397/11/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Survey of the analgesic effect of venous Paracetamol in comparison with the combination of venous Paracetamol and Propofol in the relief of acute migraine headache

Public title
Comparison of analgesic effect of Paracetamol with combination of Paracetamol and Propofol in the relief of acute migraine headache

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Failure to receive narcotic drugs or other Triptans, such as vasoconstrictor, such as Dihydroergotamine, within 24 hours before referral to the emergency department Patients treated with systemic Corticosteroids Patients with Diabetes Mellitus history, active gastrointestinal ulcers, myocardial infarction in the last week Family history of hypocalmic paralysis (for Dexamethasone)

Exclusion criteria:
Those who have kidney failure

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples are randomly divided into 8 groups in a randomized block and then will divide into 2 groups. Accordingly, based on the probability of placing the patient in a group of 8 in each block, 4 patients in group A and 4 patients in group B Will be accidental. Then, on a visit, a block is selected and will be assigned to the relevant group based on the order of the patient's arrival and the card row in each patient block.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is double-blind clinical trial study, only the The doctor is responsible for distributing the medication knows the name of the drug and the patient and other physician who registers the pain score is not aware of the type of medication taken.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences, Dr Hesabi sq., Daneshgah blvd.

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2018-05-22, 1397/03/01

Ethics committee reference number
IR.ZAUMS.REC .1397.094

Health conditions studied

1

Description of health condition studied
Acute migraine headache

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Pain

Timepoint
Pain score is recorded based on the VAS scale before treatment and 5, 10, 20, 30, and 45 minutes after treatment.

Method of measurement
By VAS or Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Paracetamol recipients - After giving explanations and obtaining the written consent of individuals to participate in the project, this group will receive 1000 mg Paracetamol.

Category
Treatment - Drugs

2

Description
Intervention group2: Receiving Paracetamol and Propofol combination - After giving explanations and obtaining written consent of individuals to participate in the project, this group will receive 500 mg Paracetamol and 0.5 mg / kg Propofol (due to combination of Paracetamol and Propofol, the dose of Paracetamol is reduced to 500 mg).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam Al Anbiya Hospital

Full name of responsible person
Zabihollah Hashemzehi

Street address
Khatam Al Anbiya Hospital, Jam-e-jam blvd.

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9815733169

Phone
+98 54 3322 0501

Email
zabih1966@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Mohsen Taheri

Street address
Zahedan University of Medical Sciences, Dr Hesabi sq., Daneshgah blvd.

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Phone
+98 54 3329 5715

Email
taheri@zaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Farahnaz Ahmadi

Position
Resident of Emergency Medicine

Latest degree
Medical doctor

Other areas of specialty/work
Emergency Medicine

Street address
Zahedan University of Medical Sciences, Dr Hesabi sq., Daneshgah blvd.

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Phone
+98 54 3329 5744

Email
farahnaz.ahmadi@zaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Farahnaz Ahmadi

Position
Resident of Emergency Medicine

Latest degree
Medical doctor

Other areas of specialty/work
Emergency Medicine

Street address
Zahedan University of Medical Sciences, Dr Hesabi sq., Daneshgah blvd.

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463
Phone
+98 54 3329 5744
Email
farahnaz.ahmadi@zaums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Farahnaz Ahmadi
Position
Resident of Emergency Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
Street address
Zahedan University of Medical Sciences, Dr Hesabi sq., Daneshgah blvd.
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5744
Email
farahnaz.ahmadi@zaums.ac.ir

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
Only part of the information, such as the main outcome information, can be shared.
When the data will become available and for how long
The start of the access period will be 6 months after the publication of the results.
To whom data/document is available
Data will only be available to scholars working in university and academic institutions.
Under which criteria data/document could be used
The data should be used only for the purpose of future studies.
From where data/document is obtainable
Visit the university vice chancellor for research.
What processes are involved for a request to access data/document
The data will be accessible by the university's research director upon confirmation of the application.
Comments