Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

Evaluating the effectiveness of intravenous Propofol plus paracetamol versus paracetamol alone in benign headaches, a randomized placebo controlled clinical trial.

Protocol summary

Study aim

Evaluating the effect of intravenous propofol and paracetamol on the pain reduction of patients with benign headaches.

Design

A clinical trial with two parallel control and case groups، randomized and double-blind.

Settings and conduct

This study was conducted in the two university-affiliated hospitals in Tehran. Patients aged over 18 years with benign headaches included in the study. The research team comprised of 4 physicians and four nurses. Participants were randomly assigned in two groups, paracetamol plus propofol, and paracetamol placebo. Medications were prepared in the covered vials by a pharmacist. The research team was blinded to the patient's assignment. Vital signs and pain intensity of the patients before and after the intervention were evaluated at 0, 10, 20, 30, 60 minutes using the numerical rating scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged over 18 years with benign headaches. Exclusion criteria: Pregnancy; Allergy to the medications; chronic liver disease; signs and symptoms of secondary headaches.

Intervention groups

The first group will receive 1gr of intravenous paracetamol in 100 ccs normal saline over 20 minutes and 1mg/kg intravenous propofol. The second group will receive 1gr of intravenous paracetamol in 100 ccs normal saline over 20 minutes and placebo.

Main outcome variables

Pain intensity using the numeric rating scale; systolic blood pressure; diastolic blood pressure; heart rate; oxygen saturation at 0,10, 20, 30, 60 minutes after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141116019971N4**
Registration date: **2019-09-02, 1398/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-02, 1398/06/11**
Update count: **0**

Registration date

2019-09-02, 1398/06/11

Registrant information

Name

Ehsan Karimi

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-19, 1398/05/28

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
Evaluating the effectiveness of intravenous Propofol plus paracetamol versus paracetamol alone in benign headaches, a randomized placebo controlled clinical trial.

Public title
Propofol plus paracetamol in benign headaches.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years and above Benign headaches
Exclusion criteria:
Suspicious to secondary headaches based on the attending physician's judgment Abnormal vital signs Variation in the level of consciousness Fever Focal neurologic defficite Pregnancy Allergy to the egg yolk, acetaminophen or propofol Neck stiffness Hepatic failure an chronic liver disease
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Computer-generated block randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
A pharmacist was providing the medication and placebo in the masked vials. Physicians were not aware of the patient's assignment. The nurse who was injecting the drug was also unaware of patients assignment.
Placebo
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
Tehran University of Medical Sciences, Poorsina Avenue, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1417653861
Approval date
2015-04-07, 1394/01/18
Ethics committee reference number
92-04-30-27786-135783

Health conditions studied

1

Description of health condition studied
Headache
ICD-10 code
R51
ICD-10 code description
Headache

Primary outcomes

1

Description
Pain intensity
Timepoint
0,10, 20, 30, 60 minutes
Method of measurement
Numeric rating scale

Secondary outcomes

1

Description
Blood pressure
Timepoint
0,10, 20, 30, 60 minutes
Method of measurement
Blood pressure cuff

2

Description
Heart rate
Timepoint
0,10, 20, 30, 60 minutes
Method of measurement
Cardiac monitoring device

3

Description
Oxygen saturation

Timepoint
0,10, 20, 30, 60 minutes
Method of measurement
Puls oxymeter

Intervention groups

1

Description
Intervention group: receives 1gr of intravenous paracetamol in 100 ccs normal saline over 20 minutes and 1mg/kg intravenous propofol. Medications: 1. Paracetamol: G.E.S. Injection 10 mg/ml,100 ml, Genpharma Co (Spain) 2. Propofol: LIPURO Injection 10mg/ml,50 ml, B.Braun (Germany) 3. Normal saline: SODIUM CHLORIDE 0.9% INF P-BOTTLE, SAMEN Co, 1L
Category
Treatment - Drugs

2

Description
Control group: receives 1gr of intravenous paracetamol in 100 ccs normal saline over 20 minutes and placebo. Medications: 1. Paracetamol: G.E.S. Injection 10 mg/ml,100 ml, Genpharma Co (Spain) 2. Normal saline: SODIUM CHLORIDE 0.9% INF P-BOTTLE, SAMEN Co, 1L 3. Placebo: Normal saline will be used as a placebo.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Compelex
Full name of responsible person
Dr Mojtaba Aghili
Street address
Imam Khomeini Hospital Complex, Keshavarz Boulevard, Dr Gharib street
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2

Recruitment center
Name of recruitment center
Sina Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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Dr. Mohammad Ali Sahraian
Street address
Vice chancellery for research and technology, 6Th Floor, Central office of Tehran University of Medical Sciences, Qods Ave, Keshavarz Boulevard
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Email
vcr@tums.ac.ir
Web page address
http://vcr.tums.ac.ir/
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
Mojtaba Aghili

Position
Assisstant Professor of Emergency Medicine

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
upon completion of the study, Individual participant data (anonymous) comprising age, gender, pain intensity, and vital signs will be released.

When the data will become available and for how long
Access to the information starts in 2020.

To whom data/document is available
All researchers have the possibility to access the data regardless of the research field.

Under which criteria data/document could be used
There are no specific criteria for data access.

From where data/document is obtainable
To request data access, please contact to Dr Ehsan Karimi. E-mail: drkarimi86@gmail.com, Phone number: 00989122493628, Address: Dr Shariati hospital,North Karegar ave, .

What processes are involved for a request to access data/document
Upon contact, data will be sent by email.

Comments