

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 3600

Email address

e-karimi@sina.tums.ac.ir

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 deficit 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

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 0000

Email

aghili220@yahoo.com

Web page address**2****Recruitment center****Name of recruitment center**

Sina Hospital

Full name of responsible person

Dr Ehsan Karimi

Street address

Sina Hospital, 30th Tir Street, Imam Khomeini Ave

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Email

drkarimi86@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8163 3685

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
Assistant Professor of Emergency Medicine
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Dr gharib Avenue, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6690 4848
Fax
Email
aghili220@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ehsan Karimialavijeh
Position
Assistant Professor of emergency medicine
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Dr Shariati hospital, North Karegar Ave
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 84901
Fax
Email
drkarimi86@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person

Ehsan Karimialavijeh
Position
Assistant Professor of emergency medicine
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Dr Shariati hospital, North Karegar Ave
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 84901
Fax
Email
drkarimi86@gmail.com
Web page address

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