

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of acetaminophen & high flow oxygen in patients with headache

Protocol summary

Study aim

Evaluation the effect of oxygen and acetaminophen on patients with headache.

Design

Clinical trial, without control group, randomized, blinded with a sample size of 168 people

Settings and conduct

At least 168 patients with headache aged 20-70 years old referred to Pursina Hospital of Rasht were divided into two groups with 100% oxygen uptake with apotolic ampoule (acetaminophen), one mg versus only apotropic injection group.

Participants/Inclusion and exclusion criteria

inclusion criteria: All patients aged 20 to 70 are eligible for admission to the emergency room with a major headache complaint. exclusion criteria: Unwillingness to participate in the plan.

Intervention groups

Group A (acetaminophen + oxygen) and group B (acetaminophen).

Main outcome variables

Study of headache reduction after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038196N1**

Registration date: **2018-06-02, 1397/03/12**

Registration timing: **retrospective**

Last update: **2018-06-02, 1397/03/12**

Update count: **0**

Registration date

2018-06-02, 1397/03/12

Registrant information

Name

Amir Hossein Salimi Kordasiabi

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

2016-06-21, 1395/04/01

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

2016-07-22, 1395/05/01

Actual recruitment end date

2017-11-21, 1396/08/30

Trial completion date

empty

Scientific title

Effect of acetaminophen & high flow oxygen in patients with headache

Public title

Study of the effect of acetaminophen and high flow oxygen In patients with headache

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Headache The need for admission due to the severity of the headache Indication of the onset of analgesic treatment for headache

Exclusion criteria:

People under the age of 20 and over 70 years Patients with CVA history Signs of fracture of the base of skull Patients unstable for hemodynamic Patients admitted with head trauma

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **168**

Actual sample size reached: **168**

Randomization (investigator's opinion)

Randomized

Randomization description

At the beginning of the study cards are written from numbers 1 to 168 (minimum sample size), then, these cards are named by another person who does not know about interventions as the group A (acetaminophen + oxygen) and group B (acetaminophen). Then, these cards are placed in a box and delivered to another person. Presenter coordinate with the professors of emergency medicine and other emergency medical assistants to randomly take a paper (type A or B) out of the box and the patients receive the treatment that is on the card when the patient is admitted to hospital with the main complaint of the headache.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient, the prescribe, as well as the person who analyze the data, do not know the type of treatment

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gilan University of Medical Sciences

Street address

Pursina Hospital-Namjoo Street-Rasht-Gilan

City

Rasht

Province

Guilan

Postal code

1234567890

Approval date

2017-11-17, 1396/08/26

Ethics committee reference number

IR.GUMS.REC.1396.289

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

G43.C

ICD-10 code description

Periodic headache syndromes in child or adult

Primary outcomes

1

Description

Pain

Timepoint

At the time of admission and two hours after prescription

Method of measurement

Visual Analage Scaling (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

The first group (acetaminophen + oxygen)Receiving oxygen 100% and high pressure (oxygen at a suitable and humid temperature that enters the patient's airway through a face mask) with an Apotel (acetaminophen) injection of one gram

Category

Treatment - Drugs

2

Description

The second group (acetaminophen): Receiving an Apotel (acetaminophen) injection of one gram

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pursina Hospital

Full name of responsible person

Dr. Sadegh Jafarpour Kooluri

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Namjoo Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences
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Email
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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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Dr. Sadegh Jafarpour Kooluri

Position
Associate professor
Latest degree
Specialist
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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only part of the information, such as information on the main outcome or the like, can be shared

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Professors and students of medical universities

Under which criteria data/document could be used

No conditions

From where data/document is obtainable

Using existing mail

What processes are involved for a request to access data/document

If available, the data will be provided to the requested person within 2 months

Comments