

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

comparing 3 different oxygen delivery methods plus intravenous ketorolac on primary headaches in emergency department

Protocol summary

Summary

Objective: comparison of three different Oxygen therapy methods as an adjunctive treatment for primary headaches. Inclusion criteria: age 18 years and above, moderate and severe primary recurrent headaches. Exclusion criteria: suspicious to secondary headache based on attending physician's judgment, abnormal vital signs, decreased consciousness, NSAIDs contraindication, Focal neurologic finding, mild pain (VAS score: 3 or less). All adult primary headache patients that meet inclusion criteria would be included. Sample size is 136 patients (34 patients for each group).first group will receive 30 mg intravenous Ketorolac + Oxygen 15lit/min through the non-rebreather mask. Second group will receive 30 mg intravenous Ketorolac + 7lit/min oxygen through 60% venture mask, third group will receive 30 mg intravenous Ketorolac + 4lit/min oxygen through nasal cannula, fourth group will receive 30 mg intravenous Ketorolac in the room air. Pain will be assessed by Visual Analog Scale at 0, 15,30,45,60 minutes of admission. The duration of the study is 6 month.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111619971N1**

Registration date: **2015-04-21, 1394/02/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-21, 1394/02/01

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

Tehran University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing 3 different oxygen delivery methods plus intravenous ketorolac on primary headaches in emergency department

Public title

Oxygen therapy in headache

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age 18 years and above; moderate and severe primary recurrent 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 finding;allergy to NSAIDs; History of peptic

ulcer diseases or gastrointestinal bleeding; pregnancy;
mild pain(Vas score: 3 or less).

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

Street address

Poursina Street, Keshavarz Boulevard

City

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 score

Timepoint

0,15,30,45,60 min

Method of measurement

Visual analog scale

Secondary outcomes**1****Description**

ED length of stay, morphine dosage, recurrence rate

Timepoint

24 hour

Method of measurement

medical document

Intervention groups**1****Description**

ketorolac 30 mg IV + o2 15 lit/min with non rebreathing mask.

Category

Treatment - Drugs

2**Description**

ketorolac 30 mg IV +o2 7 lit/min with 60% venturi mask

Category

Treatment - Drugs

3**Description**

ketorolac 30 mg IV+ o2 4 lit/min nasal

Category

Treatment - Drugs

4**Description**

ketorolac 30 mg IV + Room air

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr Shariati Hospital

Full name of responsible person

Dr Ehsan Karimi

Street address**City**

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Morteza Saidi

Street address

Poursina Street, Keshavarz Boulevard

City

Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Karimi

Position

Assistant Professor of Emergency Medicine

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty