Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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

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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, recurrencerate

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

Tehran

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
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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