

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of sublingual buprenorphine and intravenous morphine in pain relief and side effects in patients with primary headache admitted in emergency department

Protocol summary

Summary

Object: comparison of sublingual buprenorphine and intravenous morphine in pain relief and side effects in patients with primary headache admitted in emergency department. Design: randomized (randomized numbers), double blind, placebo, single center. Target sample size: 140 Exclusion criterias: patients with convulsion; cardiac disorder; liver disorder; nephrogenic disorder; metabolic disorder; temperature more than 38; patients with unstable vital sign (blood pressure under 90); pregnancy; patients with drug addiction; patients with allergy to opioid; patients who get opioid 6 hours before admit to emergency; age under 18 and age upper 55; patients who would not like arrive to study. Inclusion criterias: patients with age 15; 55 years old. Setting and conduct: we measure pain with Numeric rating scale (NRS), patients divide To two groups, control group (M group) who get intravenous morphine 0.1 mg per kg and sublingual placebo, intervention group (B group) who get sublingual buprenorphine 2mg and intravenous placebo then pain measure in times 0, 20, 40, 60 Mminutes after get drug with Numeric rating scale. Out come: without Pain with drug with less complication.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030821379N1**
Registration date: **2015-07-06, 1394/04/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-06, 1394/04/15

Registrant information

Name

Mehdi Hadipourzadeh

Name of organization / entity

Ahwaz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Ahwaz University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sublingual buprenorphine and intravenous morphine in pain relief and side effects in patients with primary headache admitted in emergency department

Public title

Comparison of sublingual buprenorphine and intravenous morphine in pain relief and side effects in patients with primary headache admitted in emergency department

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criterias: Patients with convulsion; cardiac disorder; liver disorder; nephrogenic disorder; metabolic disorder; temperature more than 38; patients with unstable vital sign (blood pressure under 90); pregnancy; patients with drug addiction; patients with allergy to opioid; patients who get opioid 6 hours before admit to emergency; age under 18 and age upper 55; patients who would not like arrive to study Inclusion criterias: patients with age 18; 55 Years old

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz University of Medical Sciences

Street address

Ahwaz University of Medical Sciences, Golestan, Ahwaz

City

Ahwaz

Postal code

Approval date

2015-05-19, 1394/02/29

Ethics committee reference number

IR.AJUMS.REC.1394.73

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

G44.2 ,G4

ICD-10 code description

Migraine, Tension-type headache, Cluster headache syndrome

Primary outcomes

1

Description

pain

Timepoint

In times 0, 20, 40, 60 minutes after get drug

Method of measurement

Numeric rating scale

Secondary outcomes

1

Description

Nausea And Vomiting

Timepoint

In times 0, 20, 40, 60 minutes after get drug

Method of measurement

With questionnaire, had or hadn't

2

Description

Blood Pressure

Timepoint

In times 0, 20, 40, 60 minutes after get drug

Method of measurement

With questionnaire, had or hadn't

3

Description

Breathing depression

Timepoint

In times 0, 20, 40, 60 minutes after get drug

Method of measurement

With questionnaire, had or hadn't

4

Description

Itch

Timepoint

In times 0, 20, 40, 60 minutes after get drug

Method of measurement

With questionnaire, had or hadn't

5

Description

Drowsiness

Timepoint

In times 0, 20, 40, 60 minutes after get drug

Method of measurement

With questionnaire, had or hadn't

6

Description

Dizziness

Timepoint

In times 0, 20, 40, 60 minutes after get drug

Method of measurement

With questionnaire, had or hadn't

Intervention groups

1

Description

Intervention group who get sublingual buprenorphine 2mg and intravenous placebo then pain measure in times 0, 20, 40, 60 minutes after get drug With Numeric Rating Scale

Category

Treatment - Drugs

2

Description

Control group who get intravenous morphine 0.1 mg per kg and sublingual placebo, Then pain measure in Times 0, 20, 40 , 60 minutes after get drug with Numeric rating scale

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Dr Hasan Barzegari

Street address

Golestan hospital, Golestan, Ahwaz

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Ahwaz University of Medical Sciences

Full name of responsible person

Dr nader saki

Street address

Ahwaz University of Medical Sciences, Golestan, Ahwaz

City

Ahwaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Ahwaz 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

Ahwaz University of Medical Sciences

Full name of responsible person

Dr Hasan Barzegari

Position

Assistant professor of Emergency

Other areas of specialty/work

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Person responsible for updating data

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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