

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Sedative Analgesic Effect of Nitrous Oxide versus Ketamine in limb fracture Pain Control , a Pilot Study. Golestan hospital emergency ward

Protocol summary

Summary

In a clinical trial study, the patients with limbs fracture who needed pain control were included in the intervention. The patients were studied in the Ahvaz Golestan Hospital General Hospital ED Department. The patients excluded from the study are those afflicted with chronic airway diseases and COPD subconscious patients with a history of reaction to NO or Ketamin a known case of psychiatric disease, patients afflicted with otitis media and patients who had food a liquids two hours before taking sedative dose. Patient over 18 years old referring to emergency ward will be randomly selected through computer random number generated method for use of one of the intravenous Ketamin or inhaled nitrous oxide. The mask is effective to the extent that the patients' breath pressure is above 5 cm H₂O or with the decrease of the breath pressure the mask breathing ceases. Ketamin receive 0.3 mg/kg intravenously. For each group, that patient's amount of pain will be registered three times with an interval five minutes using VAS score setting. The results of 2 groups will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111815446N1**
Registration date: **2014-05-29, 1393/03/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-29, 1393/03/08

Registrant information

Name

Hassan Motamed

Name of organization / entity

Emergency Department , Ahvaz Jundishapour
University of Medical Sciences , Ahvaz , Iran

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3079

Email address

motamed-h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2013-11-28, 1392/09/07

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sedative Analgesic Effect of Nitrous Oxide versus Ketamine in limb fracture Pain Control , a Pilot Study. Golestan hospital emergency ward

Public title

Comparison of Nitrous Oxided and Ketamin Sedative Analgesic Effect for Pain Control.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: any limbs fractures who are seeking for Pain Control. Exclusion Criteria: COPD; liver disease;

head injury; loss of consciousness; lung injury; asthma and patient disagreement.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Esfand st., Golestan st.

City

Ahvaz

Postal code

Approval date

2013-07-30, 1392/05/08

Ethics committee reference number

ajums.rec.1392.108

Health conditions studied

1

Description of health condition studied

Local anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

Pain relief

Timepoint

Baseline, fifth, tenth, fifteenth minutes

Method of measurement

VAS score

Secondary outcomes

1

Description

Decrease blood pressure

Timepoint

Baseline, fifth, tenth, fifteenth minutes since start of drug give

Method of measurement

Patient monitoring- blood pressure measurement

2

Description

Respiratory failleue

Timepoint

Baseline, fifth, tenth, fifteenth minutes since start of drug give

Method of measurement

Patient monitoring- blood pressure measurement

3

Description

Vomiting

Timepoint

Baseline, fifth, tenth, fifteenth minutes since start of drug give

Method of measurement

Patient monitoring- blood pressure measurement

Intervention groups

1

Description

Intervention group: nitrous oxide 50:50 intake

Category

Treatment - Drugs

2

Description

Control group: recieve ketamin 0.3 mg/kg intravenus

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan hospital

Full name of responsible person

Dr. Hassan Motamed

Street address

Ahvaz Golestan hospital, Golestaan st.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Nader Saki

Street address

Vice chancellor for research, Ahvaz University of Medical Sciences

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Hassan Motamed

Position

Emergency medicine assistant professor

Other areas of specialty/work

Street address

Golestan hospital

City

Ahvaz

Postal code

Phone

+98 61 1374 3079

Fax

Email

motamed-h@ajums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Hassan Motamed

Position

Emergency medicine assistant professor

Other areas of specialty/work

Street address

ahvaz golestan hospital

City

Ahvaz

Postal code

Phone

+98 61 1374 3079

Fax

Email

motamed-h@ajums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Hassan Motamed

Position

Emergency medicine assistant professor

Other areas of specialty/work

Street address

Golestaan hospital, Golestan st.

City

Ahvaaz

Postal code

Phone

+98 61 1374 3079

Fax

Email

motamed-h@ajums.ac.ir

Web page address

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