

# 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 H<sub>2</sub>O 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

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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*