

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of Ketamine in reduction of shivering during spinal anesthesia in orthopedic, urology and general surgeries

Protocol summary

Summary

The aim of this study is to analyze efficacy of Ketamine in reduction of shivering during spinal anesthesia in patients who are admitted for orthopedic surgery, urology surgery and general surgery and have anesthesia risk of 1, 2 and 3 and referred to operation room of Shahid Rajaei Hospital, Qazvin, Iran. Patients with age, gender, type of surgery and the same anesthesia risk are divided into two groups (control and trial). Each group includes 146 (total 292). After doing spinal anesthesia, putting the patient in the proper position of surgery, in the trial group 0.2mg/kg of Ketamine are injected intravenously. In control group, placebo (distilled water), in equal volume to Ketamine, are injected intravenously. Then the patients would be supervised by observers and the results of observations (shivering grades) are recorded in questionnaire forms. This is a doubled blind study and injectors and observers are not aware of injection contents.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903114084N1**
Registration date: **2010-11-04, 1389/08/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-11-04, 1389/08/13

Registrant information

Name

Habibolloh Mehdipoor

Name of organization / entity

Qazvin university of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Health and allied health faculty, Qazvin University of Medical sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Ketamine in reduction of shivering during spinal anesthesia in orthopedic, urology and general surgeries

Public title

Efficacy of Ketamine in reduction of shivering during spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with orthopedic, urology or general surgeries. Exclusion criteria: patients with anesthesia risk above 3.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 292

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

Qazvin University of Medical Sciences

Street address

Shahid bahonar Blvd., Rasht square

City

Qazvin

Postal code

3419915315

Approval date

empty

Ethics committee reference number

1606 / 20 / 3

Health conditions studied

1

Description of health condition studied

shivering

ICD-10 code

R25

ICD-10 code description

Abnormal involuntary movements

Primary outcomes

1

Description

shivering

Timepoint

every 5 min.

Method of measurement

Observational Grade

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ketamine 0.2mg/kg /iv after placing patient on surgical position

Category

Prevention

2

Description

Control group: placebo is injecting in equal volume of Ketamine intravenously after placed patient on surgical position.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital

Full name of responsible person

Dr. Hamid kayalha

Street address

Shahid Rajaei Hospital, Padegan Ave, Padegan Square

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Paramedical faculty, Qazvin University of Medical sciences

Full name of responsible person

Dr.Mohammad Mehdi Emam Jome

Street address

Shahid Bahonar Blvd

City

Qazvin

Grant name

از محل بودجه پژوهشی دانشکده

Grant code / Reference number

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

Yes

Title of funding source

Paramedical faculty, Qazvin 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

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Person responsible for general inquiries

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Person responsible for scientific inquiries

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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