Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the efficacy of Midazolam, Propofol , and Midazolam-Propofol in prevention of pruritis induced by intrathecal Sufentanil in patients under surgery

Protocol summary

Summary

Itching after surgery in patients under intrathecal anesthesia with opioid is a common complication that proposed treatment is not effective in all patients. we decided to compare the efficacy of 2 drugs previousely disscused for pruritis treatment. inclusion criteria include elective surgery and major surgery ; ASA class 1 or 2 . And exclusion criteria include opium addicted patients and emergent surgery. Study population are patients admitted in Imam Khomeini hospital operating room for surgery. Sample size is 90 patients, which receive one of the 3 drug groups ;propofol, midazolam and propofol and midazolam combined .outcome is the incidence and severity of pruritis every 30 minuetes during the surgery and in 24 hours after end of surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203059213N1**
Registration date: **2013-07-23, 1392/05/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-23, 1392/05/01

Registrant information

Name

Jalil Makarem

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1576

Email address

j-makarem@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Because the drugs were routinely used for anesthesia, the patient is responsible for project cost ,it includes his medical expenses

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Midazolam, Propofol , and Midazolam-Propofol in prevention of pruritis induced by intrathecal Sufentanil in patients under surgery

Public title

Comparison of the efficacy of 3 drug groups :Midazolam, Propofol , and Midazolam- Propofol in prevention of pruritis induced by anesthetic drug used for syrgery

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: age:18-65 each sex; elective surgery; major surgery ; ASA class 1 or 2; informed cosent
exclusion criteria: spinal anesthesia contraindication; opium addicted patients; emergent surgery; severe COPD; drug allergy to used drug in this study

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Tehran University of Medical Sciences Ethics Committee

Street address

Tehran University of Medical Sciences, Qods street, Keshavarz Blvd, Tehran

City

Tehran

Postal code

Approval date

2012-04-21, 1391/02/02

Ethics committee reference number

2708/130/90/د

Health conditions studied

1

Description of health condition studied

pruritus

ICD-10 code

L29.9

ICD-10 code description

Pruritus, unspecified

Primary outcomes

1

Description

pruritus

Timepoint

24 hours after begining the surgery

Method of measurement

questioning the patient about the time, area and the severity of itching

Secondary outcomes

empty

Intervention groups

1

Description

group1 : 20 mg propofol is injected as bolus ,then 50 mcg/kg/min IV infusion.

Category

Prevention

2

Description

group2 :midazolam: 0.03 mg/kg midazolam is injected as bolus dose,then 0.02 mcg/kg/min IV infusion

Category

Prevention

3

Description

group3: 10 mg propofol and 0.015 mg/kg midazolam are injectes as bolus doses , then 25 mcg/kg/min propofol and 0.01 mcg/kg/min midazolam IV infusion.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr.Jalil Makarem

Street address

Tohid square ,Tohid street , Azadi street ,Tehran ,Imam Khomeini Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Jalil Makarem

Street address

Tehran University of Medical Sciences, Poursina st, 16th Azar st, Enghelab Eslami square, Tehran

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

Tehran University of Medical Sciences

Full name of responsible person

Dr.Jalil Makarem

Position

Assistant Professor

Other areas of specialty/work

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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