

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 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 previously discussed 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 minutes 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**

2708/130/90/3

**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 beginning 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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## 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*