Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of the efficacy and complications of different doses of granisetron in prophylaxis of intrathecal sufentanil induced-pruritus in patients undergoing lower limb surgery in Emam Khomeini hospital during 1391-92

Protocol summary

Summary

In this double blind randomized clinical trial, the efficacy of tree different doses of granisetron in prophylaxis of intrathecal sufentanil induced-pruritus will study on male and female patients between 18 to 65 years old of American Society of Anesthesiologists class I,II that have consent to do spinal block for them and dont have disorders of cardiac,hepatic,renal and spinal deformity undergoing lower limb orthopedic surgery. In this study 180 patients divide in 4 groups , 30 minutes before spinal block and administration of intrathecal opioid, in first group 10 mcg/kg,second group 40 mcg/kg ,third group 60 mcg/kg granisetron and in fourth group normal saline as a placebo will infuse during 1 minutes. during surgery and after that until 24 hours,the patients will evaluate of pruritus and other probable complications caused by granisetron and finally all of these four groups will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072414149N1**
Registration date: **2013-09-07, 1392/06/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-09-07, 1392/06/16

Registrant information

Name

Samira Kazem

Name of organization / entity

Tehran University of Medical Science, School of Medicine

Country

Iran (Islamic Republic of)

Phone

+98 21 4403 3836

Email address

s_kazem@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-06-09, 1391/03/20

Expected recruitment end date

2012-12-11, 1391/09/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and complications of different doses of granisetron in prophylaxis of intrathecal sufentanil induced-pruritus in patients undergoing lower limb surgery in Emam Khomeini hospital during 1391-92

Public title

The effect of granisetron in prophylaxis of intrathecal opioid induced-pruritus

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria : ASA class I-II exclusion criteria :male

less than 18 years old; male more than 65 years old; fmale less than 18 years old; fmale more than 65 years old; ASA Class III; ASA Class IV; patient refuse from performing spinal block; patients with spinal deformities; patients with mental disorders; patients with local skin infections; history of anaphylaxis to local anesthetics,sufentanil and granisetron; patients with coagulation disorders; patients with severe hepatic disease; patients with renal function disorder; patients with body wheight more than 100 kilograms; patients dependent to opioid; patients with severe chronic obstructive pulmonary disease (FEV1 less than 600cc); height less than 150 cm or more than 180 cm; known cardiac disease; patients with long QTsyndrome

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **180**

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
Tehran University of Medical Science, Research council of Medical school

Street address
medical School of Medicine, north side of Tehran University, Poursina street

City
Tehran

Postal code
1417613151

Approval date
2012-07-01, 1391/04/11

Ethics committee reference number
399

Health conditions studied

1

Description of health condition studied
intrathecal opioid induced-pruritus

ICD-10 code
L29.8

ICD-10 code description
other pruritus

Primary outcomes

1

Description
pruritus

Timepoint
30 minutes-0.5 to 2 hours - 2 to 4 hours - 4 to 8 hours - 8 to 24 hours after intervention

Method of measurement
Visual Analogue Scales and Verbal Rating Scales for assessment of the severity of pruritus

Secondary outcomes

1

Description
pain

Timepoint
30 minutes- 0.5 to 2 hours - 2 to 4 hours - 4 to 8 hours - 8 to 24 hours after intervention

Method of measurement
Visual Analogue Scales for assessment of pain

2

Description
nausea

Timepoint
30 minutes - 0.5 to 2 hours - 2 to 4 hours - 4 to 8 hours - 8 to 24 hours after intervention

Method of measurement
observation

3

Description
vomiting

Timepoint
30 minutes - 0.5 to 2 hours - 2 to 4 hours - 4 to 8 hours - 8 to 24 hours after intervention

Method of measurement
observation

4

Description
shivering

Timepoint
30 minutes - 0.5 to 2 hours - 2 to 4 hours - 4 to 8 hours -

8 to 24 hours after intervention
Method of measurement
observation

5

Description
blood pressure
Timepoint
30 minutes - 0.5 to 2 hours - 2 to 4 hours - 4 to 8 hours - 8 to 24 hours after intervention
Method of measurement
mmHg

6

Description
haert rate
Timepoint
30 minutes - 0.5 to 2 hours - 2 to 4 hours - 4 to 8 hours - 8 to 24 hours after intervention
Method of measurement
beats/min

7

Description
respiratory rate
Timepoint
30 minutes - 0.5 to 2 hours - 2 to 4 hours - 4 to 8 hours -8 to 24 hours after intervention
Method of measurement
beats/min

8

Description
arterial oxygen saturation
Timepoint
30 minutes - 0.5 to 2 hours - 2 to 4 hours- 4 to 8 hours - 8 to 24 hours after intervention
Method of measurement
percent

9

Description
drowsiness
Timepoint
30 minutes - 0.5 to 2 hours - 2 to 4 hours - 4 to 8 hours - 8 to 24 hours after intervention
Method of measurement
Ramsey sedation score

10

Description
headache
Timepoint
30 minutes - 0.5 to 2 hours - 2 to 4 hours - 4 to 8 hours - 8 to 24 hours after intervention
Method of measurement
observation

11

Description
allergic reaction
Timepoint
30 minutes - 0.5 to 2 hours - 2 to 4 hours - 4 to 8 hours - 8 to 24 hours after intervention
Method of measurement
observation

12

Description
arrythmia
Timepoint
30 minutes - 0.5 to 2 hours - 2 to 4 hours - 4 to 8 hours - 8 to 24 hours after intervention
Method of measurement
observation

Intervention groups

1

Description
control group:normal saline as placebo 4.5 mL intravenously
Category
Placebo

2

Description
group 1 : granisetron 10 mcg/kg + normal saline up to total volume of 4.5 mL intravenously
Category
Prevention

3

Description
group 2 : granisetron 40 mcg/kg + normal saline up to total volume of 4.5 mL intravenously
Category
Prevention

4

Description
group 3 : granisetron 60 mcg/kg + normal saline up to total volume of 4.5 mL intravenously
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthopedic Operating Room, Emam Khomeini Hospital
Full name of responsible person
Dr.A.P.Zanjani, Assistant Professor, Anesthesiologist

Street address
Emam Khomeini Hospital, Keshavarz Blvd
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Dr.SH.Akhondzadeh, Research Assistant of Medical School
Street address
School of Medicine, North side of Tehran University ,Poursina street
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 Science
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 Science, School of Medicine
Full name of responsible person
Samira - Kazem
Position
Resident Anesthesia
Other areas of specialty/work
Street address
School of Medicine, North side of Tehran University,Poursina street
City
Tehran
Postal code
1417613151
Phone
+98 21 6640 0917
Fax
+98 21 6640 4377
Email
s_kazem@razi.tums.ac.ir
Web page address
http://medicine.tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Science, School of Medicine
Full name of responsible person
Dr.J.Makarem
Position
Assistant Professor, Anesthesiologist
Other areas of specialty/work
Street address
School of Medicine, North side of Tehran University, Poursina street
City
Tehran
Postal code
1417613151
Phone
+98 21 6640 0917
Fax
+98 66404377
Email
s.akhond@neda.netj_makarem@razi.tums.ac.ir
Web page address
http://medicine.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
School of Medicine, Tehran University of Medical Science
Full name of responsible person
Dr.J.Makarem
Position
Assisstant Professor of Anesthesiology
Other areas of specialty/work
Street address
School of Medicine, North side of Tehran University, Poursina street
City
Tehran
Postal code
1417613151
Phone
+98 21 6640 0917
Fax
+98 21 6640 4377
Email
j_makarem@razi.tums.ac.ir
Web page address
http://medicine.tums.ac.ir

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