Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study the effect of subcutaneous injection of naloxone to prevent pruritus caused of intrathecal injection of pethidine in minor surgeries

Protocol summary

Summary

The aim of this study was to determine the effect of subcutaneous injection of naloxone to prevent itching is caused by intrathecal injection of pethedine. This study is a clinica lstage 3 trail double-blind, placebo-controlled, single center. 105 patient condidate 60-20 years who due to Inclusion criteria: Inclusion criteria: patients condidate spinal anesthesia , Exclusion criteria: the creation of any side effects of naloxone; any cardiovascular disease; Addiction to opioids randomly selected, divide into three groups of 35 people.The first group .5 ml of sterile saline , second and third group .01 mg per kg body weight naloxone that volume has been to half ml injected subcutaneously in the anterior forearmand after 5 minute , the first and the second group analgesic lidocaine .5% and pethedine a of the space L3-L4 lumbar and the third group of patients with analgesic lidocaine.5% and pethedine plus 0.1 mg adrenaline 0.001%, are under spinal anesthesia.check list are checked after surgery, itching is responding to treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021210222N8**
Registration date: **2017-03-04, 1395/12/14**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-04, 1395/12/14

Registrant information

Name

Zahra Keivani

Name of organization / entity

Shahrekord University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1222 0016

Email address

keivani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University Of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of subcutaneous injection of naloxone to prevent pruritus caused of intrathecal injection of pethidine in minor surgeries

Public title

Study the effect of subcutaneous injection of naloxone to prevent pruritus caused of intrathecal injection of pethidine in minor surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients condidate spinal anesthesia using exclusion criteria: the creation of any side effects of naloxone any cardiovascular disease; Addiction to opioids

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

N/A

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

Ethics Committee of Shahrekord University of Medical Sciences

Street address

shahrekord university of medical sciences, Kashani street, shahrekord

City

Shahrekord

Postal code

Approval date

2017-01-15, 1395/10/26

Ethics committee reference number

IR.SKUMS.REC.1395.249

Health conditions studied

1

Description of health condition studied

itching

ICD-10 code

L24.9

ICD-10 code description

Irritant contact dermatitis, unspecified cause

Primary outcomes

1

Description

itching

Timepoint

after surgery

Method of measurement

checklist

Secondary outcomes

empty

Intervention groups

1

Description

First Group:.5 ml of sterile normal saline is injected subcutaneously in the anterior forearm and after 5 minute with lidocaine.5% and pethedine from the fourth and fifth vertebrae of lumbar space under spinal anesthesi.

Category

Prevention

2

Description

Second group: 01.% mg per kg body weight naloxone that volume has been to.5 ml is injected subcutaneously in the anterior forearm andFirst Group:.5 ml of sterile normal saline is injected subcutaneously in the anterior forearm and after 5 minute with lidocaine.5% and pethedine from the fourth and fifth vertebrae of lumbar space under spinal anesthesi.

Category

Treatment - Drugs

3

Description

Third group:01.% mg per kg body weight naloxone that volume has been to.5 ml is injected subcutaneously in the anterior forearm and after 5 minute with lidocaine half a percent and pethedine plus 0.1% mg adrenaline 0.001% from the fourth and fifth vertebrae of lumbar space under spinal anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital in Shahrekord

Full name of responsible person

Mohammad Reza Abedinzadeh

Street address

Kashani Hospital of Shahrekord University of Medical Sciences, Parastar street, shahrekord

City

shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shahrekord University of Medical Science
Full name of responsible person
Dr. Kamal Solati
Street address
shahrekord university of medical sciences, Kashani street, shahrekord
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Shahrekord 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
Shahrekord University Of Medical Sciences
Full name of responsible person
Mohammad Reza Abedinzadeh
Position
Anesthesiologist, Assistant Professor
Other areas of specialty/work
Street address
Kashani Hospital of Shahrekord University of Medical Sciences, Parastar street, shahrekord
City
Shahrekord
Postal code
Phone
+98 383322200016
Fax
Email
st-ahmadi.a@skums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Mohammad Reza Abedinzadeh
Position
Anesthesiologist, Associate Professor
Other areas of specialty/work
Street address
Kashani Hospital of Shahrekord University of Medical Sciences, Parastar street, shahrekord
City
Shahrekord
Postal code
Phone
+98 38 3222 0016
Fax
Email
st-ahmadi.a@skums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahrekord University of Medical
Full name of responsible person
Mohammad Reza Abedinzadeh
Position
Anesthesiologist, Associate Professor
Other areas of specialty/work
Street address
Kashani Hospital of Shahrekord University of Medical Sciences, Parastar street, shahrekord
City
Shahrekord
Postal code
Phone
+98 38 3222 0016
Fax
Email
st-ahmadi.a@skums.ac.ir
Web page address

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