Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of ultra low dose naloxone on post-operative ileus after caesarean section by spinal anesthesia

Protocol summary

Summary

Postoperative ileus in bowel due to loss of coordinated motility non-mechanical factors caused by their inability to pass gas and stool and food intolerance show. The patient usually nausea, vomiting, severe constipation and abdominal discomfort and pain is publish. This study is a randomized triple-blind clinical trial.The target population included all patients undergoing spinal anesthesia for cesarean section in a hospital in the exercise of Imam Khomeini (RA) is Sari in 1393-1394. Before the start of the list of subjects for the second study group, 60 patients were randomized using a computer to be determined. Sitting patients are Drpvzyshn and space L2-L3 and L3-L4 spinal puncture spinal Basvzn be done. Patients were randomly divided into two groups A and B. Group A) intervention (combination of morphine and naloxone pump PCA contains 30 mg dose of 0.25µg / kg / hr manufacturing pharmaceutical company producing the drug and the rest of the volume of 100 cc (total volume pump PCA) has become saline. group) B (control: internal composition contains 30 mg of morphine PCA pump and the rest of the volume of 100 cc (total volume pump PCA) has become saline. profile settings PCA pump would then be: the 5/0 cc bolus with Lockout 15 minutes and background infusion 2cc / h.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022426357N2**
Registration date: **2016-08-24, 1395/06/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-24, 1395/06/03

Registrant information

Name
seyed mohamad mehdi daneshpoor
Name of organization / entity
mazandaran university of medical science
Country
Iran (Islamic Republic of)
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mdaneshpour@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Science

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ultra low dose naloxone on post-operative ileus after caesarean section by spinal anesthesia

Public title

Effect of naloxone on ileus after caesarean section by spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria (inclusion criteria): The willingness of patients to participate in the study and informed

consent; first elective cesarean section under spinal anesthesia; Age> 18 years; ASA Class ¦ Exclusion criteria (exclusion criteria): Any contraindication to spinal anesthesia; Taking prokinatic; Irritable Bowel Syndrome; drug addiction;

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
mazandaran university of medical science

Street address
Sari-blvd daneshgah

City
sari

Postal code
Iran

Approval date
2015-02-27, 1393/12/08

Ethics committee reference number
IR.Mazums.rec.94

Health conditions studied

1

Description of health condition studied
ileus

ICD-10 code
K56.7

ICD-10 code description
Ileus, unspecified

Primary outcomes

1

Description
ileus

Timepoint
as soo

Method of measurement
Upon arrival to the recovery room, 30 minutes, 60 minutes, 90 minutes, 120 minutes, 6, 12 and 24 hours after operation

Secondary outcomes

1

Description
pain

Timepoint
Upon arrival to the recovery room, 30 minutes, 60 minutes, 90 minutes, 120 minutes, 6, 12 and 24 hours.

Method of measurement
VAS

2

Description
VOMITING

Timepoint
Upon arrival to the recovery room, 30 minutes, 60 minutes, 90 minutes, 120 minutes, 6, 12 and 24 hours.

Method of measurement
VAS

3

Description
NAUSEA

Timepoint
Upon arrival to the recovery room, 30 minutes, 60 minutes, 90 minutes, 120 minutes, 6, 12 and 24 hours.

Method of measurement
VAS

4

Description
Itching

Timepoint
Upon arrival to the recovery room, 30 minutes, 60 minutes, 90 minutes, 120 minutes, 6, 12 and 24 hours after surgery

Method of measurement
VAS

Intervention groups

1

Description
Group A) intervention (combination of morphine and

naloxone pump PCA contains 30 mg dose of 0.25µg / kg / hr manufacturing pharmaceutical company producing the drug and the rest of the volume of 100 cc (total volume pump PCA) has become saline.

Category

Treatment - Drugs

2

Description

group) B (control: internal composition contains 30 mg of morphine PCA pump and the rest of the volume of 100 cc (total volume pump PCA) has become saline. profile settings PCA pump would then be: the 5/0 cc bolus with Lockout 15 minute infusion 2cc / h

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

imam khomeini hospital

Full name of responsible person

atefeh hadian

Street address

amir mazandarani avenue

City

sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Science

Full name of responsible person

atefeh hadian

Street address

Imam Khomeini

City

sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Science

Full name of responsible person

Atefeh Hadian

Position

Ansthesiology Resident

Other areas of specialty/work

Street address

Sari Amirmazandarani

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Other areas of specialty/work

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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