Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of pain severity and side effects of intrathecal injection of morphine and morphine plus Naloxone in cesarian patients

Protocol summary

Study aim
Comparison of severity of pain and morphine intrathecal complications and morphine with naloxone in patients undergoing cesarean section

Design
Double-blind clinical trial with block randomized allocation and parallel group design

Settings and conduct
The patients were randomly assigned to the groups, after randomization. The collaborator who is informed to random numbers and patient grouping is responsible for registering patients' names and preparing the medication. Subsequently, Injection of the drug is done by a collaborator unaware of the type of medication And the post-operative information is collected by unbiased collaborations of the uninformed patient. After collecting enough samples, the patient's total information is shared with the first partner so that patients are embedded in both groups and statistical analysis can be done Patients will receive 10 mg of 0.5 % bupivacaine plus 100 µg of morphine intrathecaly. in addition In the case group patients will receive 20 ng naloxone of Tolid daru companies

Participants/Inclusion and exclusion criteria
patents admit in Emam hospital For cesarian ,ASA classification 1or 2 and 60 -80 Kg weight and first or second pregnancy will submit to the study and Patients who used opiate drugs before cesarean section or have consumption of any medicine to reduce itching and if spinal anesthesia was unsuccessful or if surgery prolong more than normal ; will dismissed from study

Intervention groups
Patients in both case and control group will receive 10 mg of 0.5 % bupivacaine plus 100 µg of morphine intrathecaly. in addition In the case group patients will receive 20 ng naloxone of Tolid daru companies

Main outcome variables
Patients' pain score will be evaluated based on the VAS questionnaire at 2, 4 and 6 hours after surgery and after 24 hours.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140524017811N8**
Registration date: **2018-12-10, 1397/09/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-10, 1397/09/19**
Update count: **0**

Registration date
2018-12-10, 1397/09/19

Registrant information

Name
Shayan Amjadi

Name of organization / entity
Students Research Committee,Arak Universiry of Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 86 3417 3502

Email address
sh.amjadi@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-06, 1397/08/15

Expected recruitment end date
2019-02-04, 1397/11/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pain severity and side effects of intrathecal injection of morphine and morphine plus Naloxone in cesarian patients

Public title

morphine plus Naloxone in cesarian

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patents admit in Emam hospital For cesarian ASA classification 1or 2 60 -80 Kg weight first or second pregnancy

Exclusion criteria:

Patients who used opiate drugs before cesarean section consumption of any medicine to reduce itching unsuccessful spinal anesthesia prolong surgery

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization which the patient was the randomization unit. Assignment of patients to the intervention and control group is carried out by a statistical expert by using blocks of 4 with with the help of statistical software minitab and using random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will randomly enter a group in block randomization Medications for each group are prepared by a collaborator and available to the uninformed therapist Also, the patients are not aware of the type of medication received

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Sari, Imam Sq, Joybar 3way, Start of valiye asr highway, Mazandaran University of Medical Sciences

City

sari

Province

Mazandaran

Postal code

۳۳۹۷۱۴۸۱۵۷

Approval date

2018-10-09, 1397/07/17

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.13997.044

Health conditions studied

1

Description of health condition studied

cesarean

ICD-10 code

O82

ICD-10 code description

Encounter for cesarean delivery without indication

Primary outcomes

1

Description

pain

Timepoint

The pain level will be evaluated at 2, 4, 6 and after 24 hours after surgery

Method of measurement

Visual Analogue Scale(VAS)

Secondary outcomes

1

Description

nausia

Timepoint

it will be evaluated at 2, 4, 6 and 24 hours after surgery

Method of measurement

asking the patient

2

Description

itching

Timepoint

will be evaluated at 2, 4, 6 hours after surgery

Method of measurement

asking the patient

Intervention groups

1

Description

Intervention group: Patients in both case and control group will receive 10 mg of 0.5 % bupivacaine plus 100 µg of morphine and 20 ng naloxone of Tolid daru companies intrathecaly.

Category

Treatment - Drugs

2

Description

Control group: will receive 10 mg of 0.5 % bupivacaine plus 100 µg of morphine intrathecaly

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Foad Fouladi

Street address

Imam Khomeini hospital , Amir mazandarani St, Imam Sq, Sari

City

sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3304 4000

Fax

+98 11 3336 2569

Email

mhabibi@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saiedi

Street address

Mazandaran University of Medical Sciences valiye asr highway,Joybar 3way,Imam Sq,Sari

City

sari

Province

Mazandaran

Postal code

۳۳۹۷۱۴۸۱۵۷

Phone

+98 11 3304 4001

Email

mhabibi@mazmus.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Reza Habibi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini hospital , Amir mazandarani St, Imam Sq, Sari

City

sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3304 4000

Fax

+98 11 3304 4000

Email

mhabibi@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Reza Habibi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini hospital , Amir mazandarani St, Imam Sq, Sariساری ،میدان امام، خیابان امیر مازندرانی ، بیمارستان امام خمینی شهر sari

City

sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3304 4000

Email

mhabibi@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Reza Habibi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

ساری ،میدان امام، خیابان امیر مازندرانی ، بیمارستان امام خمینی

City

sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3304 4000

Email

mhabibi@mazums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All statistical data is available after being unidentifiable

When the data will become available and for how long

The access period is up to one year after the publication of the results

To whom data/document is available

Data is available to academic researchers

Under which criteria data/document could be used

Use of information for academic research projects is allowed

From where data/document is obtainable

corresponding author Mohammad Reza Habibi Imam Khomeini hospital , Amir mazandarani St, Imam Sq, Sari +98 936 732 9790 mhabibi@mazums.ac.ir

What processes are involved for a request to access data/document

Requests for specific information should be sent by an email to the responsible author along with an explanation of why the data is needed

Comments