

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Clinical trial of comparison of intrathecal with intravenous Dexamethasone to reduce post operation complications after cesarean section due to intrathecal Morphine

Protocol summary

Summary

In this double-blind (Patient and nurse) clinical trial, 120 patients candidate for cesarean section will be randomly divided into two groups of intervention and control with table of random numbers and intrathecal and intravenous Dexamethasone are compared to reduce post operation complications after cesarean section. Spinal anesthesia will be provided in a sitting position with a spinal needle (25 Gauge) made by Dr.japanco company, China in the space between L3-L4 or L4-L5 with injection of 10 mg Marcaine 0.5% (10 mL in 2 cc) and 0.2 mg of intrathecal morphine made by Iran hormone Co. in both groups. The case group receives 8 mg intrathecal Dexamethasone injected in the same space (2 cc, made by Iran Hormone Co.) and the control group receives 8 mg Intravenous Dexamethasone made by Iran Hormone Co. in addition to 2 cc intratechal distilled water in the same vertebral space. The severity and incidence of nausea, vomiting, itching and pain will be recorded by an expert nurse or anesthesiology resident who are unaware of the study groups in recovery room and then at 1, 6, 12 and 24 hours after discharge from the recovery based on visual analog scale (VAS). If nausea and vomiting rate is higher than 4, 4 mg ondansetron made by Iran Hormone Co. will be prescribed and the injection will be recorded. Then, the patient's satisfaction is asked based on VAS. Finally, BMI, age, education level, duration of surgery and anesthesia, history of nausea and vomiting after surgery and the amount of ondansetron used 24 hours after surgery will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112631095N1**

Registration date: **2017-01-30, 1395/11/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-30, 1395/11/11

Registrant information

Name

Alieh Zamani Kiasari

Name of organization / entity

Mazandaran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 11 3335 5080

Email address

azamani@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of intrathecal with

intravenous Dexamethasone to reduce post operation complications after cesarean section due to intrathecal Morphine

Public title

Clinical trial of comparison of intrathecal with intravenous Dexamethasone to reduce post operation complications after cesarean section

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria includes informed consent and undergoing elective cesarean section. Exclusion criteria includes unwillingness of the patient to continue participating in the study, height less than 150 cm, mental Disorders, corticosteroid use, alcohol consumption and drug abuse, contraindication to receive regional anesthesia, allergy to drugs used in the study, diabetes, hypertension and receiving antiemetic medications 24 hours prior to surgery

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: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Using simple randomization and table of random numbers, patients are randomly divided into two intervention and control groups. Also, this study is double-blind and the patient and the nurse or anesthesiology resident who complete the checklist are unaware of the study groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vice chancellor for research of Mazandaran University

of Medical Science, Moalem square, Moalem street, Sari, Iran

City

Sari

Postal code

Approval date

2016-02-21, 1394/12/02

Ethics committee reference number

IR.MAZUMS.REC.94-1753 A

Health conditions studied

1

Description of health condition studied

Single delivery by caesarean section

ICD-10 code

O82

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

Nausea and vomiting

Timepoint

Recovery and then at 1, 6, 12 and 24 hours after discharge from recovery

Method of measurement

VAS

2

Description

Itching

Timepoint

Recovery and then at 1, 6, 12 and 24 hours after discharge from recovery

Method of measurement

VAS

3

Description

Pain

Timepoint

Recovery and then at 1, 6, 12 and 24 hours after discharge from recovery

Method of measurement

VAS

Secondary outcomes

1

Description

Patient Satisfaction

Timepoint

After discharge from recovery

Method of measurement

Visual analog scale

Intervention groups

1

Description

The intervention group receives 0.2 mg of intrathecal Morphine plus 8 mg of intrathecal Dexamethasone made by Iran Hormone Co. injected in L3-L4 or L4-L5 space

Category

Treatment - Drugs

2

Description

The control group receives 0.2 mg of intrathecal Morphine in inter-vertebral space and 8 mg Intravenous Dexamethasone made by Iran Hormone Co. in addition to 2 cc intratechal distilled water in the same vertebral space

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Sari

Full name of responsible person

Alieh Zamani Kiasari

Street address

Imam Khomeini Hospital, Amir Mazandarani Boulevard, Sari

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmadali Enayati

Street address

Research deputy of Mazandaran University of Medical Science, Moallem Square, Sari

City

Sari

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, Mazandaran 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

Mazandaran University of Medical Science

Full name of responsible person

Khadijeh Ghavibonyeh

Position

Anesthesiology Residents

Other areas of specialty/work

Street address

Clinical Research Development Center, Imam Khomeini Hospital, Amir Mazandarani Boulevard

City

Sari

Postal code

Phone

+98 11 3335 5080

Fax

Email

ghavibonyehk@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Science

Full name of responsible person

Alieh Zamani Kiasari

Position

Assistance professor of Anesthesiology and Intensive Care

Other areas of specialty/work

Street address

Clinical Research Development Center, Imam Khomeini Hospital, Amir Mazandarani Boulevard

City

Sari

Postal code

Phone

+98 11 3335 5080

Fax

Email

aliehzamani@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Science

Full name of responsible person

Alieh Zamani Kiasari

Position

Assistant professor of Anesthesiology and Intensive Care

Other areas of specialty/work**Street address**

Clinical Research Development Center, Imam Khomeini Hospital, Amir Mazandarani Boulevard

City

Sari

Postal code**Phone**

+98 11 3335 5080

Fax**Email**

aliezamani@yahoo.com

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