

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

A Comparison the effects of lidocaine - Dexamethasone with Lidocaine - epinephrine intrathecal on quality of sensory block in electhve cesarean sectionin .

Protocol summary

Summary

the aim of this double blinded randomized clinical trial was evaluation the efficacy of lidocaine- epinephrine or lidocaine -dexamethasone intrathecal on quality of sensory block in elective cesarean section.a total 90 ASA physical status I-II women undergoing elective cesarean section with spinal anesthesia were randomized to 3 groups.group 1:epinephrine ,group2:dexamethasone and group3:saline.The spinal anesthesia was done in sitting position using 25 gauge needle .epinephrine group recived 75mg lidocaine and 100microg ram epinephrine, dexamethasone group recived 75mg lidocaine and 4mg dexamethasone and saline group recived 75mg lidocaine and 1ml normal saline.sensory onset time and duration of senory block comparad among the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205279874N1**

Registration date: **2012-08-14, 1391/05/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-14, 1391/05/24

Registrant information

Name

Freshteh Naziri

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor Of Research Babol University of Medical Sciences

Expected recruitment start date

2012-05-04, 1391/02/15

Expected recruitment end date

2012-10-21, 1391/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison the effects of lidocaine - Dexamethasone with Lidocaine -epinephrine intrathecal on quality of sensory block in electhve cesarean sectionin .

Public title

A Comparison the effects of lidocaine - dexamethasone with Lidocaine -epinephrine intrathecal on quality of sensory block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: elective cesarean section in pregnant women 18-35 years ,ASA ClassI, II ,elective cesarean section Exclusion criteria from the study: patients with a history of alergy, psychiatric disorder, chronic pain, those taking corticosteroids , alcohol and drug dependence , emergency cesarean

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: **90**

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

Babol University Of Medical Sciences

Street address

Daneshgah Square - Ganjafrooz Avenue

City

Babol

Postal code

Approval date

2012-04-30, 1391/02/11

Ethics committee reference number

6262/30/پ/ز

Health conditions studied

1

Description of health condition studied

Other complications of Anesthesia during pregnancy

ICD-10 code

029.8

ICD-10 code description

Other complications of anaesthesia during pregnancy

Primary outcomes

1

Description

The duration of sensory block

Timepoint

Every 15 minutes until 4 dermatom regression

Method of measurement

Pin prik test with needle

2

Description

Onset of sensory block

Timepoint

Time from intrathecal injection to highest sensory level

Method of measurement

Pin prik test with needle

Secondary outcomes

1

Description

Blood pressure

Timepoint

Every 3 min to end of surgery

Method of measurement

Manometer

2

Description

Heart rate

Timepoint

Every 5 min to recovery

Method of measurement

ECG

3

Description

Nausea

Timepoint

During delivery to 24 hours

Method of measurement

Questioning from patient (having or not)

4

Description

Vomiting

Timepoint

During delivery to 24 hours

Method of measurement

Questioning from patient

5

Description

Pain

Timepoint

Recovery room to 24 hours

Method of measurement

Visual analog scale

Intervention groups

1

Description

Intrathecal injection of 75 mg lidocaine and 1 cc normal saline.

Category

Treatment - Drugs

2

Description

Intrathecal injection of 75mg lidocaine and 100 microgram epinephrine

Category

Treatment - Drugs

3

Description

Intrathecal injection of 75 lidocaine and 4mg dexamethasone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Ruhani Hospital

Full name of responsible person

Dr Freshteh Naziri

Street address

Anesthesiology Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor Of Research Babol University Of Medical Sciences

Full name of responsible person

Dr Amrolah Mostafazadeh

Street address

Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor Of Research Babol 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

Babol University Of Medical Sciences

Full name of responsible person

Dr Freshteh Naziri

Position

Assistant Professor Of Anesthesiology

Other areas of specialty/work

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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