Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 compard 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
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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/ژ/پ

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 regretion

Method of measurement

Pin prik test with needle

2

Description

Onset of sensory block

Timepoint

Time from intrathecal injection to highst 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

Hear rate

Timepoint

Every 5 min to recovery

Method of measurement

ECG

3

Description

Nausea

Timepoint

During delivery to24 hours

Method of measurement

Questioning from patient(having or not)

4

Description

Vomiting

Timepoint

During delivery to 24 hours

Method of measurement

Questiening 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
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Anesthesiology Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue
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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
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Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue
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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

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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