Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Impact of Intratechal Clonidine in analgesia in elective cesarean

Protocol summary

Summary

Pain is one of the most post operative complications in cesarean. Nowadays local anesthesia has been more used due to its advantages. One hundred sixty six pregnant women aged 15-40, with ASA class I or II, are going to enter this double blind randomized trial. They should fulfill the criteria of elective cesarean without neonatal distress. Control group will receive 75-100 mg Lidocaine 5% (based on their height) while case group will receive the same plus 75 mcg Intratechal Clonidine. Pulse rate and blood pressure will be assessed each 5 minutes for the first 20 minutes; each 10 minutes till recovery discharge, then each 4 hours for 12 hours. Analgesia will be assessed just after recovery admission, then each 4 hours for 12 hours, and so, APGAR score will be assessed at first, fifth and tenth minutes after delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901212080N3**
Registration date: **2010-05-17, 1389/02/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-05-17, 1389/02/27

Registrant information

Name

Afsaneh Norouzi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1313 7474

Email address

norouzi.a@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of research & education of Arak University of Medical Sciences

Expected recruitment start date

2010-04-10, 1389/01/21

Expected recruitment end date

2010-09-12, 1389/06/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of Intratechal Clonidine in analgesia in elective cesarean

Public title

Impact of Intratechal Clonidine in analgesia in elective cesarean

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. age: 15-40 2. ASA score I, II 3. Elective and term cesarean; Exclusion criteria: 1. Emergent cesarean 2. Fetal perinatal distress due to thick meconium, deculment or low APGAR score 3. Patient`s low compliance for entering the study and spinal analgesia 4. positive history of preeclampsia, chronic hypertension, consumption of B-blockers, Antipsychotics or Anti depressants 5. Perioperative Anti emetics use

Age

From **15 years** old to **40 years** old

Gender

Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **166**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Arak University of Medical Sciences
Street address
Alamhoda St.
City
Arak
Postal code
Approval date
empty
Ethics committee reference number
88-65-2

Health conditions studied

1

Description of health condition studied
elective cesarean
ICD-10 code
O82.0
ICD-10 code description
Delivery by elective caesarean section

Primary outcomes

1

Description
analgesia
Timepoint
Immediately after recovery admission then each 4 hours for 12 hours
Method of measurement
VAS(Visual Analage Scale)

Secondary outcomes

1

Description
mother`s pulse rate & blood pressure
Timepoint
each 5 minutes for the first 20 minutes,each 10 minutes till recovery discharge,each 4 hours for 12 hours
Method of measurement
physical exam & check list

2

Description
neonate`s APGAR score
Timepoint
first,fifth and tenth minutes
Method of measurement
check list

Intervention groups

1

Description
75-100 mg Intratechal Lidocaine 5%
Category
Treatment - Drugs

2

Description
75-100 mg Intratechal Lidocaine 5%+75 mcg Intratechal Clonidine
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Dr. Afsaneh Norouzi
Street address
Emam Khomeiny street
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak university of medical sciences
Full name of responsible person
Saeed Changizi Ashtiyani
Street address

Alamhoda st.

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Afsaneh Norouzi

Position

Assistant professor,Anesthesiologist

Other areas of specialty/work

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Person responsible for updating data

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Saran Lotfollahzade

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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