

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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
Street address
 Valiasr hospital
City
 Arak
Postal code
Phone
 +98 86122247900
Fax
Email
 norouzi.a@arakmu.ac.ir
Web page address

Person responsible for scientific 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
Street address
 Valiasr hospital
City
 Arak
Postal code
Phone
 +98 86122247900
Fax
Email
 norouzi.a@arakmu.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
 Arak University of Medical Sciences
Full name of responsible person
 Saran Lotfollahzade
Position
 Medical student
Other areas of specialty/work
Street address
 Vaaliasr hospital
City
 Arak
Postal code
Phone
 +98 86122247900
Fax
Email
 h23nn23h@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