Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of frequency of cesarean section and the average of delivery phases between Epidural analgesia versus no analgesia in labor

Protocol summary

Summary

Aim of this study comparison of frequency of cesarean section and the average of delivery phases between Epidural analgesia versus no analgesia in labor. This study is clinical trials and double blind.120 patients will divide in two groups. Women will done delivery with epidural anesthesia (4-6 milliliter Marcain 0/125 percent and single dose 5 micro gram Fentanyl and preservative dose Marcain 0/125 percent and 0/002 percent in 6-10 milliliter in hours) and women pregnant will perform delivery without analgesia. We will record incidence cesarean and mean of time of delivery phases after delivery. Inclusion criteria: pregnant woman; single fetus; pregnant women candidates vaginal delivery; pregnant women candidates epidural; nuliparous; ASA class I and II; 37 to 42 weeks Exclusion criteria: Mothers with more than one fetus; multiparty mothers; patients referring to urgency; Patients with topical anesthetics and narcotic; block placenta infection; failure in epidural anesthesia

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102420258N63**
Registration date: **2017-11-16, 1396/08/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-16, 1396/08/25

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor and Research, Arak University of Medical Sciences

Expected recruitment start date

2017-06-05, 1396/03/15

Expected recruitment end date

2019-06-05, 1398/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of frequency of cesarean section and the average of delivery phases between Epidural analgesia versus no analgesia in labor

Public title

Comparison of frequency of cesarean section and the average of delivery phases between Epidural analgesia versus no analgesia in labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnant woman; single fetus; pregnant women candidates vaginal delivery; pregnant women candidates epidural; nuliparous; ASA class I and II; 37 to 42 weeks Exclusion criteria: Mothers with more than one fetus; multiparty mothers; patients referring to urgency; Patients with topical anesthetics and narcotic;

block placenta infection; failure in epidural anesthesia

Age
No age limit

Gender
Male

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
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee Arak University Of Medical Sciences

Street address
Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City
Arak

Postal code
38149578558

Approval date
2017-05-22, 1396/03/01

Ethics committee reference number
IR.ARAKMU.REC.1396.38

Health conditions studied

1

Description of health condition studied
Delivery

ICD-10 code
O80

ICD-10 code description
Single spontaneous delivery

Primary outcomes

1

Description
incidence cesarean

Timepoint
after delivery

Method of measurement
mount

2

Description
Mean of time of delivery phases

Timepoint
after delivery

Method of measurement
Minute

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Women will done delivery with epidural anesthesia (4-6 milliliter Marcain 0/125 percent and single dose 5 micro gram Fentanyl and preservative dose Marcain 0/125 percent and 0/002 percent in 6-10 milliliter in hours)

Category
Treatment - Drugs

2

Description
Control group: Delivery is performed without analgesia.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani hospital

Full name of responsible person
Dr Maryam Shokrpour

Street address
Taleghani hospital, Emam Khomeini street

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person
Dr Anoshirvani

Street address
Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

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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 for research, 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
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Full name of responsible person
Dr Maryam Shokrpour

Position
Faculty member, Gynechologist

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