

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 square, 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

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Vice chancellor for research, Payambar Azam
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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

Arak University of Medical Sciences

Full name of responsible person

Dr Maryam Shokrpour

Position

Faculty member, Gynechologist

Other areas of specialty/work

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Position

Faculty member, Anesthesiologist

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