Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparison stage of vaginal delivery in painless labor with epidural &spinal analgesia

Protocol summary

Summary

The aim of this study was to compare two methods of labor with epidural and spinal analgesia in pregnant women in Taleghani Hospital in Arak.In this study, 90 patients were randomly divided into three groups epidural analgesia in labor, spinal analgesia in labor and control group. Inclusion criteria: All pregnant women between 37-42 weeks; ASA class I and II; prim gravid; cervical dilation 3 -4 cm; absence of fever and systemic infection or other disease; lack of coagulopathy; age 18-40. Exclusion criteria: failure epidural and Spinal analgesia; sensitivity to opioids; mothers with gestational age below 37 weeks; mothers with multiple fetus. Cervix dilation record in delivery. Vital signs, oxygen saturation, blood pressure and breathing rate maternal and fetal heart rate record every 15 minutes .After delivery, researcher records Apgar score , fetal heart rate and vital signs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050420258N8**
Registration date: **2016-05-29, 1395/03/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-29, 1395/03/09

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Arak University Of Medical Science

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison stage of vaginal delivery in painless labor with epidural &spinal analgesia

Public title

Comparison stage of vaginal delivery in painless labor with epidural &spinal analgesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All pregnant women gestational age between 37-42 weeks; ASA class I and II; primigravida; dilatation of cervix 3-4 cm; lack of systemic infection or fever and other diseases; lack of sensitivity opioid; absence of coagulopathy; age 18-40 Exclusion criteria: ASA class two and three; failure epidural and spainal anasthesia; sensivity to opioid; mothers with gestational age below 37 weeks; mothers with more than one fetus fetus

Age

From **18 years** old to **40 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)

Not blinded

Blinding description

Placebo

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

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Postal code

Approval date

2016-02-22, 1394/12/03

Ethics committee reference number

IR.ARAKMU.REC.1394.297

Health conditions studied

1

Description of health condition studied

Delivery

ICD-10 code

O80.8

ICD-10 code description

Other single spontaneous delivery

Primary outcomes

1

Description

oxygen saturation

Timepoint

every 15 minute

Method of measurement

oxymeter

2

Description

heart rate

Timepoint

every 15 minute

Method of measurement

count

3

Description

respiratory rate

Timepoint

every 15 minute

Method of measurement

count

4

Description

Fetal heart rate

Timepoint

every 15 minute

Method of measurement

sony cate

5

Description

Labor progress

Timepoint

every 15 minute

Method of measurement

centimeter

6

Description

Apgar

Timepoint

After delivery

Method of measurement

Apgar scale

Secondary outcomes

empty

Intervention groups

1

Description

The first group of 30 pregnant women have an epidural.

Category

Diagnosis

2

Description
In the control group of 30 pregnant women delivery without anything.
Category
Diagnosis

3

Description
In the second group involved 30 pregnant women receiving spinal anesthesia.
Category
Diagnosis

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
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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 Mohammad Rafiee
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Research Center, 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

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Person responsible for updating data

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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