Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Comparison the Apgar score and incidence of cesarean in women undergoing spinal and epidural analgesia during painless delivery methods

Protocol summary

Summary

Aim of this study is comparison the Apgar score and incidence of cesarean in women undergoing spinal and epidural analgesia during painless delivery methods. This study is clinical trial and single blind. We will enter 126 pregnant women with gestational age 37-42 weeks. All women is pregnant and singleton pregnancy and primigravide. We will assign pregnant women in two groups (epidural analgesia and spinal analgesia). We will epidural analgesia in first group. We will spinal analgesia in second group. We check dilatation in cervix and uterus contraction before delivery. We check incidence cesarean and Apgar in fetus and arterial blood gas after birth. We will send sample of neonatal arterial blood gas (HCO3, PH, po2, co2) to laboratory after delivery. Inclusion criteria: pregnant women undergoing labor analgesia referred to Taleghani Hospital in Arak; prime gravid; ASA I and II; gestational age 37-42 week; singleton pregnancy Exclusion criteria: sensitivity to local drugs and narcotics; failure in painless childbirth; ASA class III and IV; patients with mental disorders such as depression, anxiety; patients with gastrointestinal disorders; patients with sleep disorders related to premenstrual syndrome; any use of tranquilizers and sleeping pills

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050920258N46**
Registration date: **2017-06-21, 1396/03/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-21, 1396/03/31

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research, Arak University of Medical Sciences

Expected recruitment start date

2017-02-28, 1395/12/10

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Apgar score and incidence of cesarean in women undergoing spinal and epidural analgesia during painless delivery methods

Public title

incidence of cesarean in women with spinal and epidural analgesia method

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women undergoing labor analgesia referred to Taleghani Hospital in Arak; prime gravid; ASA I and II; gestational age 37-42 week; singleton pregnancy Exclusion criteria: sensitivity to local drugs and narcotics; failure in painless childbirth; ASA class III and IV; patients with mental disorders such as depression, anxiety; patients with gastrointestinal disorders; patients with sleep disorders related to premenstrual syndrome; any use of tranquilizers and sleeping pills

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

patients and analyzer are blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Dr Mohammad Rafiei, Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City

Arak

Postal code

38149578558

Approval date

2017-02-20, 1395/12/02

Ethics committee reference number

IR.ARAKMU.REC.1395.392

Health conditions studied

1

Description of health condition studied

painless delivery

ICD-10 code

O80

ICD-10 code description

Single spontaneous delivery

2

Description of health condition studied

spinal and epidural anesthesia

ICD-10 code

O29.5

ICD-10 code description

Other complications of spinal and epidural anaesthesia during pregnancy

Primary outcomes

1

Description

dilatation in cervix

Timepoint

before delivery every 2 hours

Method of measurement

clinical examination

2

Description

uterus contraction

Timepoint

before delivery every 1 hours

Method of measurement

clinical observation

3

Description

incidence cesarean

Timepoint

after delivery

Method of measurement

count

4

Description

Apgar

Timepoint

one and fifth minute after delivery

Method of measurement

Apgar scale

5

Description

arterial blood gas

Timepoint

after delivery

Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: epidural block for delivery
Category
Treatment - Other

2

Description
Intervention group: spinal analgesia for delivery
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
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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

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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