

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Clinical trial comparison of labor phases in painless delivery with epidural analgesia and Entonox

Protocol summary

Summary

This study was randomized clinical trial that was no blind study. Aim of study is comparison of labor phases in painless delivery with epidural analgesia and Entonox administration. This study was conducted on 90 pregnant women referred to Taleghani Hospital in Arak, Iran. Inclusion criteria: primigravida women; singleton pregnancies; term pregnancy of 37 to 42 weeks; no medical diseases; cervical dilation of 3 to 4 centimeter. Exclusion criteria: multiparous; multiple pregnancy; Preterm labor; Post-term labor. The first group (n=30) received epidural analgesia with injection of 0.125 percent Marcaine and Fentanyl (5 micro gram). The second group (n=30) received general analgesia with Entonox gas. In this study, the third group consisted of 30 pregnant women who were considered as control subjects receiving no medication for labor pain relief. Fetal heart rate was controlled every 15 minutes, and the duration of each labor phase was accurately calculated in minutes. With regards to labor progress, cervical examination was performed every two hours until full dilation of the cervix. This process continued until the infant was born, and the delivery was complete. Finally, neonatal Apgar scores were recorded in prepared forms by residents of gynecology. Comparison of the study groups was performed in terms of the duration of the first and second phases of labor, frequency of cesarean delivery, neonatal Apgar scores, and prevalence of postoperative complications (e.g., headache, nausea, vomiting, and backache).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051820258N9**

Registration date: **2016-11-17, 1395/08/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-17, 1395/08/27

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

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f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research of Arak University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparison of labor phases in painless delivery with epidural analgesia and Entonox

Public title

Clinical trial comparison of labor phases in painless delivery with epidural analgesia and Entonox

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: primigravida women; singleton pregnancies; term pregnancy of 37 to 42 weeks; no medical diseases; cervical dilation 3 - 4 centimeter
Exclusion criteria: multiparous; multiple pregnancy; Preterm labor; Postterm labor

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

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
Randomize by Random Number Table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of Arak University Of Medical Sciences

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

City
Arak

Postal code
848176941

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
90-116-3

Health conditions studied

1

Description of health condition studied
Delivery

ICD-10 code

O80.0

ICD-10 code description
Spontaneous vertex delivery

Primary outcomes

1

Description
Fetal heart rate

Timepoint
every 15 minute

Method of measurement
count

2

Description
Cervix dilatation

Timepoint
every 2 hours

Method of measurement
centimeter

3

Description
Apgar

Timepoint
after operation

Method of measurement
Apgar scale

4

Description
complications after delivery

Timepoint
after operation

Method of measurement
question

Secondary outcomes

empty

Intervention groups

1

Description
The third group consisted of 30 pregnant women who were considered as control subjects receiving no medication for labor pain relief

Category
Treatment - Other

2

Description
The first group (n=30) received epidural analgesia with injection of 0.125 percent Marcaine and Fentanyl (5 micro gram).

Category

Treatment - Other

3**Description**

The second group (n=30) received general analgesia with Entonox gas.

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 of Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Rafiee

Street address

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

City

Arak

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 of 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 Alireza Kamali

Position

Anesthesiologist

Other areas of specialty/work**Street address**

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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Phone

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Medicine department

Full name of responsible person

Dr Alireza Kamali

Position

Anesthesiologist

Other areas of specialty/work**Street address**

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Arak University Of Medical Sciences

Full name of responsible person

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Position

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Email

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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