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

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Name of organization / entity
Arak University of Medical Sciences
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Iran (Islamic Republic of)
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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 centimeterv 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
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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
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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