Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of efficacy of painless delivery with epidural analgesia with Bupivacain and Rupivacain in womwn candidating Analgesia labor

Protocol summary

Study aim

Reducing the pain and suffering of labor, which encourages more mothers to deliver normal labor and reduce the stress of labor pain.

Design

This study is a randomized clinical trial (Randomized clinical trial) that is done in double blinds for all pregnant women referred to Taleghani hospital in Arak who are candidates for normal delivery. In this study, 112 patients with normal delivery were randomly divided into two equal groups of epidural delivery with bupivacaine and rupivacaine.

Settings and conduct

For both groups of pregnant women, a questionnaire asking for demographic information, cesarean section and mean delivery phases is completed.

Participants/Inclusion and exclusion criteria

Entry requirements: single pregnant mothers and vaginal delivery candidates, mothers with grade 1 and grade 2 ASA, mothers between the weeks 42-37 who are perfectly graduated and have an epidural analgesic satisfaction Conditions of failure to enter:failure in the epidural analgesia and pregnant mothers who are candidates for cesarean section for emergency reasons

Intervention groups

After obtaining informed consent, 112 pregnant women will be subjected to natural epidural analgesia (epidural analgesia) with bupivacaine or ropivacaine. After receiving 3-5 cc / kg of crystalloid fluid and placing the required monitoring in Sitting from L3-L4 or L4-L5 space using gage20 needle under epidural analgesia with bupivacaine or rupivacaine, then an epidural catheter is fixed. Patients use a 4-6 cc marcaine, 125.0% and 5 µg fentanyl as single dose block epidermis. For preservative dosage, the combination of marcaine is 125% and fentanyl% 002/0 is used at 6-10 cc / h.

Main outcome variables

Mean of motor blocker, mean of Apgar score of 1 and 5 neonates, mean of use of labor aid tools, mean satisfaction of patients, mean cesarean section, mean duration of second stage of labor, average active period of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180903040936N1**
Registration date: **2019-01-05, 1397/10/15**
Registration timing: **prospective**

Last update: **2019-01-05, 1397/10/15**
Update count: **0**

Registration date

2019-01-05, 1397/10/15

Registrant information

Name

Narges Anousheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4449 7630

Email address

nargesanousheh1994@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-10, 1398/03/20

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of painless delivery with epidural analgesia with Bupivacain and Rupivacain in womwn candidating Analgesia labor

Public title

The effect of Bupivacaine and Ropivacaine on labor Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers with one fetus Pregnant mothers who are candidates for vaginal delivery (Physiological delivery) Nullipar pregnant mothers are candidates for vaginal delivery Pregnant women referring to Taleghani Hospital with informed consent to participate in the study. Mothers with ASA grade one and two Pregnant mothers between the weeks 37-42 Who are perfectly pregnant Pregnant mothers who are candidates for vaginal delivery, who are satisfied with epidertal analgesia

Exclusion criteria:

Patients in the epidural group who undergo epidural block failure after an epidural analgesia. Pregnant mothers who are candidates for cesarean section for emergency reasons (such as placental abruption, umbilical cord prolapse, etc.).

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random numbers table, patients randomly divided into two groups of painless epidural delivery with bupivacaine and rupivacaine.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, only the anesthetist responsible for the study is aware of the type of study and the studied groups, while the patients are under the epiderdal analgesia and are not aware of the type of injectable drug.Also intern is responsible for the plan that is responsible for filling the questionnaire. It is not aware of the type of groups in terms of injectable drugs, and only knows the groups based on A and B, and completes questionnaires on the basis of it.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Sardasht, Basij Square, next to Amiralmomenin Hospital, Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-09-21, 1397/06/30

Ethics committee reference number

IR.ARAKMU.REC.1397.134

Health conditions studied

1

Description of health condition studied

Epidural analgesia with two drugs, Bupivacaine and Rupivacaine

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Average cesarean section

Timepoint

After intervention, observing the progression of labor and the occurrence of problems requires intervention

Method of measurement

Examination

2

Description

Average active delivery time

Timepoint

After the intervention, when the cervical dilatation reaches 4 to 8 centimeters

Method of measurement

Examination

3

Description
Average duration of second stage of labor
Timepoint
After the intervention, from the beginning of the full dilation of the uterus until the birth of the baby
Method of measurement
Examination

4

Description
The average satisfaction of the patient
Timepoint
2 hours after intervention
Method of measurement
Based on satisfaction checklist

5

Description
Number of use of labor aid tool
Timepoint
Up to 3 hours after intervention
Method of measurement
Number

6

Description
Mean Apgar score of 1 and 5 minutes
Timepoint
After the intervention, 1 and 5 minutes after childbirth
Method of measurement
Apgar score check list

7

Description
Average motor blocking effect
Timepoint
After intervention, up to 2 hours after childbirth
Method of measurement
Scoring patient in the checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:In the first group, after obtaining informed consent, 56 pregnant mothers with natural epidural analgesia (epidural analgesia) are contracted with bupivacaine. The patients received 3-5 cc / kg of crystalloid fluid and placed the necessary monitoring In sitting mode, the L3-L4 or L4-L5 space is inserted into the epidural analgesia using the gauge20 needle, then the epidural catheter is fixed. Patients in this group use a 4-6 cc marcaine, 125.0% and 5 µg fentanyl as single dose block epithelium. For preservative dosage, the combination of marcaine is 125% and fentanyl 002/0 is used at 6-10cc / h.
Category
Treatment - Drugs

2

Description
Intervention group: In the second group, the rupivacaine group, after obtaining informed consent, 56 pregnant mothers will be subjected to oral aphrodisiacs with epidural analgesia (epidural analgesia) with ropivacaine. Patients after taking 3-5 cc / kg of crystalloid fluid and placing sequestered monitoring from L3-L4 or L4-L5 space using gage20 needle under epidural analgesia with rupivacaine and then fix epidural catheter . Patients in this group use a 4-6 cc marcaine, 125.0% and 5 µg fentanyl as single dose block epithelium. For preservative dosage, the combination of marcaine is 125% and fentanyl% 002/0 is used at 6-10 cc / h.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Narges Anousheh
Street address
West Side of Imam Khomeini Street,Next to Gas Co
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad Arjmandzadegan
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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
Arak University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Narges Anousheh
Position
Medical Student
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available