

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of adding sufentanil and dexamethasone to ropivacaine 0.1% in painless labor with epidural anesthesia

Protocol summary

Study aim

Comparison of the effect of adding Sufentanil and Dexamethasone to Ropivacaine 0.1% in painless labor using epidural anesthesia.

Design

Clinical trial without control group, with parallel-groups, double-blind, randomized, phase 3 clinical trial on 104 patients. Randomization.com online software and block randomization method will be used for randomization.

Settings and conduct

In this study, the number of 104 term pregnant patients who are candidates for natural pain-free delivery in Taleghani Hospital in Arak city will be studied. Patients are randomly divided by the anesthesiologist into A and B groups. In both groups, the drugs used for the intervention are the same in terms of transparency and color, and the anesthesiologist labeled each of them A and B. The used syringes are also of the same shape, same color, and completely similar, and in order to comply with blinding, the volume of 10 cc is brought by the anesthetist so that they will not be able to identify the contents of the solution from their appearance. The patients and the intern responsible for evaluating the patients were not aware of the type of groups and therefore the plan will be implemented in a double-blind manner.

Participants/Inclusion and exclusion criteria

Inclusion criteria: term pregnancy, singleton pregnancy.
Exclusion criteria: heart, lung, kidney and liver diseases, allergy to used drugs, coagulopathy, spinal deformity

Intervention groups

In the first intervention group, 8 mg of dexamethasone (Alborz Daru-Iran) which was increased to 10 cc with 0.1% ropivacaine (Darman Yab Daru-Iran) and in the second intervention group, 0.25 mg per cc of the drug Sufentanil (Daroopaksh-Iran) mixed with 10 cc of Ropivacaine 0.1% (DarmanYab Daro-Iran) will be slowly injected by the anesthesiologist in the epidural space.

Main outcome variables

Duration of painlessness, headache, nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220912055952N1**

Registration date: **2022-09-24, 1401/07/02**

Registration timing: **prospective**

Last update: **2022-09-24, 1401/07/02**

Update count: **0**

Registration date

2022-09-24, 1401/07/02

Registrant information

Name

Setayesh Hashemi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-07, 1401/07/15

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of adding sufentanil and dexamethasone to ropivacaine 0.1% in painless labor with epidural anesthesia

Public title

Comparison of adding sufentanil and dexamethasone to ropivacaine 0.1% in painless labor

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Term pregnancy Singleton pregnancy

Exclusion criteria:

Allergy to any of the drugs used The presence of spinal deformities Presence of coagulopathy History of heart/pulmonary/kidney/liver disease

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the restricted randomization method of the block randomization type. The size of all the blocks is equal and due to having two groups, there should be an equal number of states A and B in each block, which due to the volume of four blocks, there were six different states for the blocks, which are: AABB, ABAB, ABBA BBAA, BABA, BAAB. In order to conceal, we use allocation concealment, which refers to the method used to perform a random sequence on the participants in the study, so that the allocated group is not known before the allocation of the individual. The cards randomly and by re-replacing the selection and order of the blocks determine the order of placing the patients in groups A and B. A person who has no knowledge about the research will be used to select the cards on which the six states of blocks of four were written.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, in order to observe the blinding of the patients, the anesthesiologist will completely randomly divide them into two groups receiving the mixture of ropivacaine and dexamethasone (group A) and the mixture of ropivacaine and fentanyl (group B). In both groups, the drugs used for the intervention are the same in terms of transparency and color, and the anesthesiologist has labeled each of them A and B. The

syringes used are also the same shape, the same color, and completely similar, and to comply with blinding, the volume is 10 cc. It is delivered by the anesthesiologist in such a way that the anesthesiologist and patients and the intern responsible for data recording will not be able to identify the content of the solution from their appearance. The intern responsible for the project did not know the type of study groups from the beginning and is only responsible for filling out the questionnaires of the project and therefore the project will be implemented in a double-blind manner. In other words, the patient and the anesthesiologist responsible for drug injection and the intern responsible for data recording will be blind.

Placebo

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

Payambar azam complex, Basij Sq., Sardasht Town

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Approval date

2022-07-03, 1401/04/12

Ethics committee reference number

IR.ARAKMU.REC.1401.105

Health conditions studied**1****Description of health condition studied**

Painless labor

ICD-10 code

O80.0

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes**1****Description**

Duration of pain relief

Timepoint

At 15, 30 and 60 minutes after epidural injection

Method of measurement

Visual Analogue Scale of pain

Secondary outcomes**1****Description**

Headache

Timepoint

Up to 6 hours after delivery

Method of measurement

Clinical interview

2**Description**

Nausea

Timepoint

Up to 6 hours after delivery

Method of measurement

Clinical interview

Intervention groups**1****Description**

The first intervention group: in 52 patients, 8 mg of dexamethasone (Alborz Daru-Iran) which was increased to 10 cc with 0.1% ropivacaine (Darmanyab Daru-Iran) will be slowly injecting by an anesthesiologist in the epidural space.

Category

Treatment - Drugs

2**Description**

The second intervention group: in 52 patients, the amount of 0.25 mg per cc of sufentanil drug (Daru paksh-Iran) mixed with 10 cc of ropivacaine 0.1% (Darmanyab Daru-Iran) will be slowly injecting by an anesthesiologist in the epidural space.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Taleghani Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Setayesh Hashemi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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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