Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of adding dexmedetomidine and sufentanil to ropivacaine in patients who are candidates for epidural painless labour

Protocol summary

Study aim

This study compares the effect of adding dexmedetomidine versus sufentanil as adjuvants to epidural ropivacaine on labor analgesia quality, maternal hemodynamics, labor duration, cesarean rate, and neonatal outcomes in primigravid women

Design

A phase III, double-blind randomized controlled trial with parallel groups conducted on 104 pregnant women candidates for epidural labor analgesia. Participants are allocated into two equal groups of 52 (ropivacaine + sufentanil vs. ropivacaine + dexmedetomidine). Randomization is performed using permuted blocks of four generated via Excel RAND function and concealed in sequentially numbered sealed envelopes.

Settings and conduct

This phase III, double-blind randomized controlled trial with parallel groups enrolls 104 participants at Taleghani Hospital, Arak. Randomization uses permuted blocks of four via Excel RAND function with sealed envelopes. Blinding is maintained through identical unlabeled syringes prepared by an independent anesthesiologist

Participants/Inclusion and exclusion criteria

Inclusion criteria include primigravid women with singleton pregnancies candidates for epidural labor analgesia, written informed consent, and no contraindication to epidural anesthesia. Exclusion criteria Hypersensitivity to drugs, contraindication to epidural, multiple gestation, multiparity, abnormal fetal presentation, cervical dilation >8 cm, uncontrolled systemic disease, psychiatric disorder or addiction, and history of lumbar spine surgery

Intervention groups

Group I : ropivacaine 0.1% + sufentanil 0.25 µg/mL (total 20 µg), 10 mL epidural bolus. Group II : ropivacaine 0.1% + dexmedetomidine 0.1 µg/kg, 10 mL epidural bolus.

Main outcome variables

Primary outcomes include pain intensity (VAS) at baseline, 5, 15, 30, and 60 minutes post-injection, analgesia duration, and neonatal Apgar scores at 1 and 5 minutes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260521069470N1**
Registration date: **2026-06-14, 1405/03/24**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-14, 1405/03/24**
Update count: **0**

Registration date

2026-06-14, 1405/03/24

Registrant information

Name

saba khalii

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3532

Email address

a.sadogh@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-13, 1405/03/23

Expected recruitment end date

2026-08-01, 1405/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of adding dexmedetomidine and sufentanil to ropivacaine in patients who are candidates for epidural painless labour

Public title
Comparing two drug adjuvants (dexmedetomidine and sufentanil) in epidural pain-free labour

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women candidates for painless delivery referred to Sina Rezaei Ashtiani Hospital, Arak Nulliparous women (first delivery) Singleton pregnancy Use of ropivacaine as the base local anaesthetic No known allergy to ropivacaine, dexmedetomidine, or sufentanil Written informed consent No contraindication to epidural anaesthesia

Exclusion criteria:
Known hypersensitivity or allergy to ropivacaine, dexmedetomidine, or sufentanil Presence of absolute or relative contraindications to epidural anesthesia (including coagulation disorders, local infection at injection site, or raised intracranial pressure) Multiple gestation (twins or higher) Multiparous women (previous vaginal delivery or cesarean section) Non-vertex fetal presentation Uncontrolled systemic diseases (uncontrolled diabetes mellitus, severe preeclampsia, significant cardiac disease) Severe psychiatric disorders or opioid/substance dependence Inability to provide written informed consent Cervical dilation greater than 8 cm at time of presentation (advanced active phase) Prior lumbar spinal surgery precluding successful epidural placement

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **204**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a permuted block randomization method will be used to allocate participants into two equal groups. Prior to the commencement of the study, a randomization sequence will be generated using statistical software (R or SPSS) based on balanced blocks of four. The possible permutations within each block include AABB, ABAB, BABA, BBAA, ABBA, and BAAB, where A denotes Group I (ropivacaine + sufentanil) and B denotes Group II (ropivacaine + dexmedetomidine). The generated randomization sequence will be placed in sequentially numbered, sealed, and opaque envelopes, which will be prepared and securely maintained by an independent person not involved in the study execution or data collection. Following confirmation of eligibility criteria and obtainment of written informed consent from each participant, the corresponding envelope will be opened in sequential order and the participant will be allocated to the designated group. Study medications will be prepared by an independent anesthesiologist who is aware of the randomization sequence; both drug combinations will be drawn into identical, unlabeled syringes of the same appearance and volume, ensuring that the patient, the administering anesthesiologist, and the data recorder remain blinded to group assignment throughout the entire study period, thereby maintaining a rigorous double-blind design.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drugs prepared in advance by the anaesthesia technician, labelled A/B in identical 10 mL syringes of the same appearance and colour Patient, administering anaesthesiologist, and data-recording intern (triple-blind in practice)

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
Payambar Azam Complex, Sardasht Town

City
Arak

Province
Markazi

Postal code
3848176341

Approval date
2026-05-16, 1405/02/26

Ethics committee reference number
IR.ARAKMU.REC.1405.076

Health conditions studied

1

Description of health condition studied
Labour pain / Epidural analgesia for labour

ICD-10 code
O74.6
ICD-10 code description
Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes

1

Description
Labour pain intensity
Timepoint
Before intervention and at 5, 15, 30, and 60 min after epidural catheter placement
Method of measurement
Visual Analogue Scale (VAS) 0–10

Secondary outcomes

1

Description
Duration of analgesia
Timepoint
From onset of analgesia to first supplemental analgesia request or end of delivery
Method of measurement
Recorded in minutes by the assigned intern

2

Description
Neonatal Apgar score at 1 and 5 minutes
Timepoint
At 1 and 5 minutes post-delivery
Method of measurement
Apgar scoring (0–10) by attending midwife or physician

Intervention groups

1

Description
Epidural injection of 10 cc of 0.1% ropivacaine solution and 20 micrograms of sufentanil in the L2/L3 or L4/L5 intervertebral space in the active phase of labor (dilation greater than 4 cm). Sufentanil will be obtained from Abu Raihan Company and dexmedetomide from Eksir Pharmaceuticals
Category
Diagnosis

2

Description
Epidural injection of 10 cc of 0.1% ropivacaine solution and 0.1 micrograms/kilogram of dexmedetomidine in the L2/L3 or L4/L5 intervertebral space in the active phase of labor (dilation greater than 4 cm) and sufentanil from Abu Raihan Company and dexmedetomidine: Eksir Pharmaceuticals
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
saba khalili
Street address
Payambar Azam Complex, Sardasht Town
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3814957558
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Behzad Khansarinejad
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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
saba khalili
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Position
Resident
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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
Not applicable
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