

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effects of epidural and spinal anesthesia on the neonate blood gas born through normal delivery: a randomized clinical trial

Protocol summary

Study aim

To assess the effects of epidural and spinal anesthesia on the neonate blood gas born through normal delivery

Design

This is a randomized clinical trial, phase II, in which 90 eligible pregnant women will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible pregnant women who will refer to Fatemieh Hospital in Hamadan City during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 35 years; A pregnant woman; First or second delivery; Gestational age of 37 weeks or more; Singleton; Cephalic presentation
Exclusion criteria: Contraindication of normal delivery such as placenta Previa, breech presentation or transverse presentation; Fetus weight above 4.5 kg; History of cesarean; Heart disease, Asthma, or renal failure

Intervention groups

Intervention group: Epidural anesthesia with Bupivacaine 25% single dose
Control group: Spinal anesthesia with Bupivacaine 25% single dose

Main outcome variables

Primary outcome: Pain severity
Apgar score
The pH mean of umbilical cord

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N256**

Registration date: **2019-01-06, 1397/10/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-06, 1397/10/16**

Update count: **0**

Registration date

2019-01-06, 1397/10/16

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of epidural and spinal anesthesia on the neonate blood gas born through normal delivery: a randomized clinical trial

Public title

Comparison of the effects of epidural and spinal

anesthesia on the neonate blood gas born through normal delivery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 35 years; A pregnant woman; First or second delivery; Gestational age of 37 week or more; Singleton; Cephalic presentation
Exclusion criteria:
Contraindication of normal delivery such as placenta Previa, breech presentation or transverse presentation; Fetus weight above 4.5 kg; History of cesarean; Heart disease, Asthma, or renal failure

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
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on every two sheets the name of each treatment. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan
Province
Hamadan
Postal code
6517838695

Approval date

2018-11-03, 1397/08/12

Ethics committee reference number

IR.UMSHA.REC.1397.496

Health conditions studied

1

Description of health condition studied

Birth asphyxia

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Pain severity

Timepoint

† 10 and 30 minutes of delivery

Method of measurement

By using visual analog scale (VAS)

2

Description

Apgar score

Timepoint

At 1 and 5 minutes after delivery

Method of measurement

By clinical examination

3

Description

The pH mean of umbilical cord

Timepoint

Immediately after delivery

Method of measurement

Through a laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Epidural anesthesia with Bupivacaine
25% single dose

Category

Treatment - Drugs

2

Description

Control group: Spinal anesthesia with Bupivacaine 25% single dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Dr Khatereh Maboodi

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Province

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Postal code

6517838695

Phone

+98 81 3828 3939

Email

khatereh.mail@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Khatereh Maboodi

Position

Gynecologic Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Soghra Rabiei

Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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