

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of delivery rate and duration of second stage of labor in sleeping versus sitting position in nulliparous women undergoing epidural analgesia

Protocol summary

Study aim

Comparison of vaginal delivery and length of the second stage of labor in mothers with standing and lying position in nulliparous women with analgesic epidural

Design

A randomized, single-blind clinical trial on 528 patients. The list of block randomization is used for randomization.

Settings and conduct

This clinical trial will be performed at Arash Hospital. In this study, 528 mothers who received epidural anesthesia during the active phase of normal delivery are included in the study and are randomly divided into two groups. The first group has a standing position in full dilatation and the other group has a lying position at the same time. Then, the duration of the second stage of labor and the type of labor and maternal satisfaction are compared in the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: singleton pregnancy, nulliparous women, aged 18-35 years old, 37 and 42 weeks of gestation, with cephalic presentation (vertex), in the second stage of labor, under epidural anesthesia from the beginning of the active phase (4 to 6 cm of cervix dilatation) Exclusion criteria: Chorionic disease, drug user, addiction, maternal bleeding.

Intervention groups

The first group has a standing position in full dilatation until delivery and the other group has a lying position at the same time. Then the two groups give birth in the lithotomy position.

Main outcome variables

Kind of delivery and the length of second delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121006011020N13**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

Registration date

2020-10-28, 1399/08/07

Registrant information

Name

Maryam Khoshideh

Name of organization / entity

Tehran University of Medical Sciences, Arash Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 0909

Email address

khooshide@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-10, 1399/05/20

Expected recruitment end date

2021-12-11, 1400/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of delivery rate and duration of second stage

of labor in sleeping versus sitting position in nulliparous women undergoing epidural analgesia

Public title

Comparison of delivery rate and duration of labor in sleeping versus sitting position in women undergoing epidural analgesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Nulliparous Single pregnancy with cephalic presentation 18-35 years old Term pregnancy(37-42 weeks of pregnancy)

Exclusion criteria:

Drug user Having Chronic Disease Addiction Maternal bleeding

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **528**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 528 people, with 264 people in each group. The Block randomization method was designed by Epithemiologist using www.sealedenvelope.com. The number of blocks considered is 4.

Blinding (investigator's opinion)

Single blinded

Blinding description

The type of intervention was written in the envelope and arranged based on the black randomization list, each time the Dr confirmed that the patient was eligible, the envelope is given to the Dr by the midwife who is no person in the research. the mother and the Outcome assessor are aware of the intervention and the statistical analysis is done by someone who is unaware

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical

Sciences

Street address

Qods St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-04-21, 1399/02/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.045

Health conditions studied

1

Description of health condition studied

Labor

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes

1

Description

The kind of delivery

Timepoint

After delivery

Method of measurement

The observation

2

Description

The length of the second stage of labor

Timepoint

Full dilatation to birth

Method of measurement

Clock

3

Description

Apgar

Timepoint

1 and 5 minutes after birth

Method of measurement

Observation

4

Description

3 rd and 4 rd laceration

Timepoint

After birth

Method of measurement

Observation

+98 21 7771 9922

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hosparash@tums.ac.ir

5

Description

Mother's satisfaction

Timepoint

After delivery

Method of measurement

Questionnaire

6

Description

Pain score

Timepoint

Every 15 minute from full dilatation until delivery

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group has a standing position (standing or sitting position) in full cervix dilatation until delivery then gives birth in a lithotomy position

Category

Other

2

Description

Intervention group: The second group has a lying position (into left, right or back) in full cervix dilatation until delivery then gives birth in a lithotomy position

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women's Hospital

Full name of responsible person

Dr Maryam Khooshide

Street address

Tehran pars

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Tehran

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1653915981

Phone

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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Maryam Khoshideh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
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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