Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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 Noliparous 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 (vortex), 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 deliver and the lenght 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)

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+98 21 7788 0909

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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

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
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Tehran pars
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

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Position
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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