Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of maternal and neonatal outcomes between two delivery positions of hands & knees and lithotomy in hospitalized multiparous women

Protocol summary

Study aim

comparison of maternal and neonatal outcomes between two delivery positions (lithotomy and hands& knees) in multiparous women in selected hospitals of Isfahan

Design

clinical trial with two intervention groups; with parallel groups; single blinded; randomized by sealed, opaque packets by random selection; on 72 multiparous women

Settings and conduct

In delivery room, After full dilatation of cervix, the participants will place in hands& knees or lithotomy position and maternal and neonatal outcome will be evaluated. The participants will not be blind. sampling is done in Asgarie hospital, Shaid Beheshti educational treatment search center, motahary hospital, hoiiy Zahra educational treatment search center

Participants/Inclusion and exclusion criteria

Inclusion criteria: ability of mother to place in the considered position; indication for normal vaginal birth
Exclusion criteria: contraindication for normal vaginal delivery; history of medical and psychological disorders

Intervention groups

First intervention group include multiparous women who locate in lithotomy position for birth. Second intervention group include multiparous women who locate in hands&knees position for birth.

Main outcome variables

Duration of the second stage, active phase of the second stage and the third stage of delivery; severity of perceived pain by mother immediately after cutting cord and after placenta delivery; volume of lost blood in the third and fourth stages of delivery; shoulder dystocia; differences between hemoglobin at hospitalization time and 6 hours after birth; differences between hematocrit at hospitalization time and 6 hours after birth; severity of perineal tear; mother satisfaction; neonatal APGAR score; neonatal hospitalization need; neonatal resuscitation need; resuscitation level of neonate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091001002531N5**
Registration date: **2021-11-30, 1400/09/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-30, 1400/09/09**
Update count: **0**

Registration date

2021-11-30, 1400/09/09

Registrant information

Name

Tahmineh Dadkhahtehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

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dadkhah-tehrani@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of maternal and neonatal outcomes between two delivery positions of hands & knees and lithotomy in hospitalized multiparous women

Public title
Comparison of maternal and neonatal outcomes between two delivery positions

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
History of delivery in lithotomy position normal physical and psychological condition during labor term/single/alive fetus with cephalic presentation without anomalies dilatation of cervix about 8 centimeter fetal weight 2500-4000 gram ability of mother to place in the considered position having no sever obstetrics complications such as sever preeclampsia, placenta abruption

Exclusion criteria:
history of cesarean section or uterus surgery contraindication for normal vaginal birth use of epidural analgesia or other medication method of analgesia history of medical and psychological disorders

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
To allocate the participants to two group (lithotomy and hands&knees) randomly, the researcher will ask mothers to take a sealed opaque package out of 90 randomly. 45 packages contains questionnaires and checklists coded 1(related to lithotomy group) and 45 packages contains the same questionnaires and checklists coded 2(related to hands&knees group). It will be written code 1 or code 2 instead of lithotomy or hands&knees on the questionnaires and checklists in order to the data analyzer could be blinded. This process will continue until having at least 36 samples in both groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Data analyzer is blinded because he/she dose not know the meaning of code 1 and 2 that is written on the questionnaires or checklists.

Placebo
Not used

Assignment
Parallel

Other design features
if the number of sealed package is considered 72(36 lithotomy and 36 hands&knees) , after completion of 36 samples of one group , the remained samples of other group will be allocated to their groups without randomization and randomization concealment will not be conducted. So, 45 packages will be prepared and sampling will be conducted until having at least 36 samples in each group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Box 57, nursing and midwifery faculty, Isfahan university of medical sciences, Hezar-jerib street

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Postal code
8174673461

Approval date
2021-07-24, 1400/05/02

Ethics committee reference number
IR.MUI.NUREMA.REC.1400.086

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The duration of the second stage of delivery

Timepoint
From the full dilatation to the birth.

Method of measurement
The duration of time is measured by chronometer

2

Description
The duration of the active phase of the second stage

Timepoint
From the beginning of active pushing till the birth of

newborn

Method of measurement

The duration of time is measured by a chronometer

3

Description

Duration of the third stage of delivery

Timepoint

From neonate birth to placenta delivery

Method of measurement

The duration of time is measured by a chronometer

4

Description

The score of severity of perceived pain in the second stage by mother immediately after cutting cord and after placenta delivery

Timepoint

Immediately after cutting cord and after placenta delivery

Method of measurement

The short form of Macgill pain questionnaire

5

Description

The volume of lost blood in the third and fourth stages of delivery

Timepoint

from birth of newborn till one hour after placenta delivery

Method of measurement

The volume of lost blood is measured by a researcher-made scaled reservoir rubber-sheet

6

Description

Shoulder dystocia

Timepoint

At birth time

Method of measurement

Observation

7

Description

Severity of perineal tear

Timepoint

After placenta delivery

Method of measurement

Observation

8

Description

Mother satisfaction

Timepoint

one hour after placenta delivery

Method of measurement

Satisfaction is measured by researcher-made quetionnaire

9

Description

Neonatal APGAR score

Timepoint

1 and 5 minutes after newborn birth

Method of measurement

Observation

10

Description

Neonatal need to hospitalization

Timepoint

After newborn birth

Method of measurement

Observation

11

Description

Neonatal need to resuscitation

Timepoint

After newborn birth

Method of measurement

Observation

Secondary outcomes

1

Description

difference between hemoglobin and hematocrit at hospitalization time and 6 hours after birth

Timepoint

hospitalization time and 6 hours after birth

Method of measurement

laboratory test of hemoglobin and hematocrit

2

Description

resuscitation level of neonate

Timepoint

after newborn birth

Method of measurement

observation

Intervention groups

1

Description

Intervention group1: After full dilatation of cervix, the participant is located in hands and knees position. The researcher records the precise times of full dilatation, spontaneous pushing, baby birth, placenta birth, and 1 hour after placenta birth is applying by chronometer. Probable shoulder dystocia and resuscitation of newborn with degree of resuscitation are recorded. After newborn

birth, mother will return to supine position and a scaled reservoir pad is located beneath the mother's buttocks and perineum until 1 hour after placenta birth to measure and record the volume of lost blood in 3th and 4th stages. Perineum is observed to assess the degree of tear. Severity of pain in the second stage is measured by Mcgill questionnaire through asking mother twice (immediately after cutting cord, at start of breastfeeding after placenta birth). APGAR score is determined using APGAR table 1 and 5 minute after birth. Satisfaction questionnaire is completed through asking mother 1 hour after placenta birth.The newborn is weighted using a digital scale during one hour after birth. Hemoglobin and hematocrit are recorded using the results of laboratory tests at hospitalization time and 6 hours after birth. Probable hospitalization of newborn and its cause is recorded. In all cases, delivery is done by main researcher and the measurements are done by the second researcher.

Category

Prevention

2

Description

Intervention group2: After full dilatation of cervix, the mother is located in lithotomy position on a 30 degree elevated bed. All measurements and data gatherings are conducted like hands and knees position group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Askaryeh hospital

Full name of responsible person

Tahmineh Dadkhahtehrani

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2

Recruitment center

Name of recruitment center

Shahid Beheshti education treatment search center

Full name of responsible person

Tahmineh Dadkhah Tehrani

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3

Recruitment center

Name of recruitment center

Motahari hospital

Full name of responsible person

Tahmineh Dadkhahtehrani

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4

Recruitment center

Name of recruitment center

Holly Zahra education treatment search center

Full name of responsible person

Tahmineh Dadkhahtehrani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Tahmineh Dadkhah Tehrani

Position
Instructor of midwifery faculty member

Latest degree
Master

Other areas of specialty/work
Postpartum rehabilitation

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Position
Instructor of Midwifery, Faculty member

Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available