

# 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, hoiyy 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)

##### Phone

+98 31 3792 7596

##### Email address

dadkhahtehrani@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

**City**

Isfahan

**Province**

Isfahan

**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

questionnaire

**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

##### Street address

Askaryeh hospital, askaryeh street, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8199753966

##### Phone

+98 31 3225 0041

##### Email

tdtahmineh@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti education treatment search center

##### Full name of responsible person

Tahmineh Dadkhahtehrani

##### Street address

Shahid Beheshti education treatment search center, Felezi bridge, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

5354181848

##### Phone

+98 31 3234 6338

##### Email

tdtahmineh@gmail.com

### 3

#### Recruitment center

##### Name of recruitment center

Motahari hospital

##### Full name of responsible person

Tahmineh Dadkhahtehrani

##### Street address

Motahari hospital, Zobahan highway

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8491813113

##### Phone

+98 31 5265 3131

##### Email

tdtahmineh@gmail.com

### 4

#### Recruitment center

##### Name of recruitment center

Holly Zahra education treatment search center

##### Full name of responsible person

Tahmineh Dadkhahtehrani

##### Street address

Holly Zahra education treatment search center, Ayatoallah Ghafari street, Zeinabieh street, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

3311181971

##### Phone

+98 31 3552 0011

##### Email

tdtahmineh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr.Mansoor Siavash

**Street address**

The deputy of search and technology, building 4,  
Isfahan University of Medical Sciences, Hezarjerib  
street, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 3335 9933

**Email**

emrc@mui.ac.ir

**Web page address**

[https://isid.research.ac.ir/Mansoor\\_SiavashDastjerdi](https://isid.research.ac.ir/Mansoor_SiavashDastjerdi)

**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

**Street address**

Faculty of Nursing & Midwifery, Isfahan University of  
Medical Science, hezarjerib street, Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73465

**Phone**

+98 31 3792 7596

**Email**

tdtahmineh@gmail.com

**Person responsible for scientific 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

**Street address**

Faculty of Nursing & Midwifery, Isfahan University of  
Medical Science, hezarjerib street.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73465

**Phone**

+98 31 3792 7596

**Email**

tdtahmineh@gmail.com

**Person responsible for updating data**

**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**

Midwifery

**Street address**

Faculty of Nursing & Midwifery, Isfahan University of  
Medical Science, hezarjerib street.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73465

**Phone**

+98 31 3792 7596

**Email**

tdtahmineh@gmail.com

**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