

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Investigating the effect of optimized birthing bed stirrups on the mother's birth experience

#### Protocol summary

##### Study aim

Investigating the effect of optimized birthing bed stirrups on the mothers birth experience

##### Design

Two arms parallel-group randomized trial. the sample size determined 31 for each group and a total of 62. In this study, the randomization method will be a randomized block design with a block size 4.

##### Settings and conduct

Pregnant women who come to Baharlu Hospital for a vaginal birth, if they meet the inclusion criteria will enter the study, will be randomly selected in the intervention and control groups, and will use the optimized and traditional birthing bed stirrups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: BMI at delivery less than 29; Gestational age greater than 37 weeks; Cervical dilatation of 10 cm; Absence of obstetrical or medical complications of pregnancy; Absence of motor disability  
Exclusion criteria: Occurrence of birth complications; Precipitated labor; Instrumental delivery

##### Intervention groups

Intervention group: Women in the intervention group will use birthing beds with optimized stirrups during childbirth. The standard questionnaire will be completed by the researcher two hours after the mother gives birth.  
Control group: women in the control group will use traditional birthing bed stirrups during childbirth. The standard questionnaire will be completed by the researcher two hours after the mother gives birth.

##### Main outcome variables

Comfort, ease, satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160808029255N13**

Registration date: **2023-07-11, 1402/04/20**

Registration timing: **prospective**

Last update: **2023-07-11, 1402/04/20**

Update count: **0**

##### Registration date

2023-07-11, 1402/04/20

##### Registrant information

###### Name

Raziyeh Maasoumi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6105 4214

###### Email address

r\_masoumi@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2023-11-21, 1402/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of optimized birthing bed stirrups on the mother's birth experience

##### Public title

Investigating the effect birthing bed stirrups on the

mother's birth experience

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

BMI at delivery less than 29 Gestational age greater than 37 weeks Cervical dilatation of 10 cm Absence of obstetrical or medical complications of pregnancy (such as diabetes, gestational hypertension, preeclampsia).

Absence of motor disability

### Exclusion criteria:

Occurrence of birth complications (such as birth dystocia, fetal heart rate disorders) Precipitated labor Instrumental delivery

## Age

No age limit

## Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 62

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization will be done by block method and using the randomization table made with Random Allocation Software with blocks of four and individual randomization units. In order to hide the random allocation from the researcher, envelopes are prepared as many as the sample size, and each of the random sequences created is recorded on paper and placed inside the envelope, and finally, the lids of the envelopes are glued. At the time of registration of people, based on the order of samples, one of the envelopes will be opened and the assigned group of that sample will be determined.

## 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 Tehran University of Medical Sciences

##### Street address

Faculty of Nursing and Midwifery, South Nosrat Ave., Towhid Sq.

## City

Tehran

## Province

Tehran

## Postal code

1419733171

## Approval date

2023-07-04, 1402/04/13

## Ethics committee reference number

IR.TUMS.FNM.REC.1402.080

## Health conditions studied

### 1

#### Description of health condition studied

Experience of using bed stirrups (comfort, ease, and satisfaction)

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

comfort of using Birthing bed stirrups

#### Timepoint

2 hours after childbirth

#### Method of measurement

experience of using Birthing bed stirrups questionnaire

### 2

#### Description

ease of using Birthing bed stirrups

#### Timepoint

2 hours after childbirth

#### Method of measurement

experience of using Birthing bed stirrups questionnaire

### 3

#### Description

satisfaction of using Birthing bed stirrups

#### Timepoint

2 hours after childbirth

#### Method of measurement

experience of using Birthing bed stirrups questionnaire

## Secondary outcomes

### 1

#### Description

Patient safety

#### Timepoint

2 hours after childbirth

#### Method of measurement

Patient safety questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Women in the intervention group will use birthing beds with optimized stirrups during childbirth. The researcher will complete the standard questionnaire two hours after the mother gives birth. The optimized stirrups have been patented and are the product of the core technology development of Pars reproductive health technologies.

#### Category

N/A

### 2

#### Description

Control group: women in the control group will use traditional birthing bed stirrups during childbirth. The standard questionnaire will be completed by the researcher two hours after the mother gives birth.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Baharloo Hospital

##### Full name of responsible person

Raziyeh Maasoumi

##### Street address

Tehran, Keshavarz Blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

##### Phone

+98 21 9116 0000

##### Email

r\_masoumi@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Fotouhi, the Vice Chancellor of Research at  
Tehran University of Medical Sciences

##### Street address

Keshavarz Blv., Qods St.

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

##### Phone

+98 21 8163 3698

##### Email

afotouhi@tums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

No

##### 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

Raziyeh Maasoumi

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Reproductive Health

##### Street address

Faculty of Nursing and Midwifery, East Nosrath.,  
Towhid Sq.,

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733171

##### Phone

+98 21 6105 4214

##### Email

r\_masoumi@sina.tums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Raziyeh Maasoumi

##### Position

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sexology

**Street address**

Faculty of Nursing and Midwifery, East Nosrat.,

Towhid Sq.,

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 21 6105 4214

**Email**

r\_masoumi@sina.tums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Raziyeh Maasoumi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

Faculty of Nursing and Midwifery, East Nosrat, Towhid

Sq.,

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 21 6105 4214

**Email**

r\_masoumi@sina.tums.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is 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**

Not applicable

**Title and more details about the data/document**

Data of the study would be available after the unrecognizable process of participants.

**When the data will become available and for how long**

6 months after publishing the results

**To whom data/document is available**

Research results would be available for academic researchers

**Under which criteria data/document could be used**

Research results would be available for same researches

**From where data/document is obtainable**

Dr. Raziyeh Maasoumi email: r\_masoumi@sina.tums.ac.ir

**What processes are involved for a request to access data/document**

Sending a request by email attendance to the office of corresponding of project presentation the reasons for similarity of two projects studying the proposal by corresponding of project final decision making with corresponding author access of data in office of corresponding author

**Comments**