Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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