Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of pelvic movements with the birth ball in the active phase of labor on the anterior rotation of the fetal head in cases of posterior occiput (OP): A randomized controlled trial

Protocol summary

Study aim
effect of pelvic movements with the birth ball in the active phase of labor on the anterior rotation of the fetal head in cases of posterior occiput (OP)

Design
The study is a two-arm randomized clinical trial with a parallel design with a control group. The permutation block method will be used for randomization. The number of participants in each group is 26 people.

Settings and conduct
Location: Sina Ahvaz Hospital. There is no blinding. A delivery ball is provided to a group and routine care is provided to a group

Participants/Inclusion and exclusion criteria
inclusion criteria: Pregnant women with spontaneous labor and posterior occiput fetus exclusion criteria: high Risk delivery

Intervention groups
Pelvic movements with the birthing ball in the intervention group Routine labor care in the control group

Main outcome variables
The frequency of anterior head rotation in posterior occiput fetuses in the active phase of labor The frequency of posterior occiput stable at the time of delivery Cervical dilatation process Cervical dilation process The process of fetal head descent Length of delivery Oxytocin volume to enhance labor Severity of labor pain Type of delivery

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20090719002204N5**
Registration date: **2024-08-20, 1403/05/30**
Registration timing: **prospective**

Last update: **2024-08-20, 1403/05/30**
Update count: **0**

Registration date
2024-08-20, 1403/05/30

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-09-22, 1403/07/01
Expected recruitment end date
2024-12-21, 1403/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of pelvic movements with the birth ball in the active phase of labor on the anterior rotation of the fetal head in cases of posterior occiput (OP): A randomized controlled trial

Public title

The effect of pelvic movements with the birth ball in the active phase of labor on the anterior rotation of the fetal head in cases of posterior occiput (OP): A randomized controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being interested in participating in the study age of at least 18 years and a maximum of 45 years low-risk pregnancy able to understand the Persian language primiparous and multiparous women singleton fetus in vertex presentation intact membranes not suffering from diseases chronic gestational age 37 to 42 weeks normal pelvic examination (to remove the bias, all examinations will be performed by an experienced person with 20 years of clinical work in the maternity hospital) 4 cm dilation of the cervix having at least three spontaneous uterine contractions of 40 seconds in ten minutes spontaneous start of labor estimation of fetal weight based on late pregnancy ultrasound between 2500 and 4000 grams/ position of the posterior occiput of the fetus during hospitalization in the active phase

Exclusion criteria:

previous cesarean Occurrence of any dangerous symptoms that risk labor and require medical intervention Withdrawal at any time from the study

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize the samples, we will use the "permutation block randomization" method using a reliable website to generate random sequences. 52 samples are assigned to two intervention (26 people) and control (26 people) groups. The random block sequence to determine the groups will be randomly generated using the randomization website www.sealedenvelope.com. The size of the blocks in this study will be different (4 blocks and 8 blocks) in order to create more variety in the allocation of samples.

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

Research Ethics Committees of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794.

Approval date

2024-07-20, 1403/04/30

Ethics committee reference number

IR.AJUMS.REC.1403.170

Health conditions studied

1

Description of health condition studied

Position of the posterior occiput of the fetal head

ICD-10 code

O64.0

ICD-10 code description

Obstructed labor due to incomplete rotation of fetal head

Primary outcomes

1

Description

Frequency of anterior rotation of the fetal head

Timepoint

Every two hours

Method of measurement

Portable ultrasound

Secondary outcomes

1

Description

Cervical dilatation process

Timepoint

Every two hours

Method of measurement

Vaginal examination

2

Description

Cervical effacement process

Timepoint

Every two hours

Method of measurement

Vaginal examination

3

Description
first labor stage duration
Timepoint
at end of the first stage
Method of measurement
Partograph

4

Description
labor pain
Timepoint
every 2 hours
Method of measurement
visual analogue scale

5

Description
Persistent posterior occiput
Timepoint
At the time of delivery
Method of measurement
observation

Intervention groups

1

Description
Intervention group: pelvic movements with birth ball. In the intervention group, from dilation of 4 cm and in case of having three spontaneous contractions of the uterus in ten minutes with a duration of at least 40 seconds, pelvic exercises with a birthing ball will be started in such a way that the mother will spread her legs shoulder-width apart and sit on the ball. For safety and to prevent falling, he will hold the protective bar next to the bed with both hands. The researcher will also be behind him for more assurance. Pelvic movements on the ball will be circular movements and the direction of rotation will be determined by the position of the fetal head. Since the main objective of our study is the rotation of the fetal head towards the mother's front (OA); Therefore, in left posterior occiput (LOP) fetuses, the direction of pelvic rotation will be to the right (clockwise) and in right posterior occiput (ROP) fetuses, the direction of pelvic rotation will be to the left (counterclockwise).
Category
Treatment - Devices

2

Description
Control group: routine care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Sina hospital
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Somayeh Makvandi
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Sponsors / Funding sources

1

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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
Ahvaz 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
Ahvaz University of Medical Sciences
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Dr. Somayeh Makavndi
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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
no information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not 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
Not applicable
Data Dictionary
Not applicable