Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the effect of walking and using ball on labor intensity and duration of labor in primipar mothers

Protocol summary

Study aim

Comparison of the effect of walking in labor and the use of delivery balls on the duration and severity of labor pain in nulliparous women

Design

This study is a clinical trial study in which 40 people in the first intervention group, 40 people in the second intervention group and 40 people in the control group are selected and enter the study and people from different groups are not in contact with each other. Sampling method is available and simple random assignment and random number table are used. If the numbers 1, 2, and 3 are selected, the individuals are in group A (delivery ball), the numbers 4, 5, and 6 are in group B (walking), and the numbers 7, 8, and 9 are in group C (control group).

Settings and conduct

The location of the project is Razi Hospital in Ahvaz. In the intermittent or intermittent ball group, sit on the ball for at least 15 minutes per hour and move the pelvis forward, backward, left and right. In the intermittent or intermittent walking group. Walk for at least 15 minutes during one hour, and if the mother is in the control group, she does not have a dominant position and is free.

Participants/Inclusion and exclusion criteria

Low-risk nulliparous pregnant women; Term pregnancy; Single pregnancy ; Cephalic display; NST satisfactory; Spontaneous and painless labor; Accept participation in the study Taking physiological delivery classes;

Intervention groups

This study consists of three groups. There are two intervention groups and one control group. The first intervention group is the effect of walking and the second intervention group is the effect of the delivery ball.

Main outcome variables

walk Childbirth ball Intensity of pain in the active phase of labor Intensity of pain in the second stage of labor The length of the active phase of labor The length of the second stage of labor Mother's age BMI Economic level education Job

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200816048429N1**
Registration date: **2020-10-10, 1399/07/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-10, 1399/07/19**
Update count: **0**

Registration date

2020-10-10, 1399/07/19

Registrant information

Name

Samira Maleki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3252 3020

Email address

sam.maleki69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of walking and using ball on labor intensity and duration of labor in primipar mothers

Public title

"Walking and using ball on labor"

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Low-risk primiparous pregnant women; Term pregnancy; Single pregnancy; Cephalic presentation; Satisfactory NST; Labor spontaneously and without Analgesia؛ Accept participation in the study؛ Passing physiological delivery classes.

Exclusion criteria:

Women with maternal fetal complication; Fetus with abnormal Presentation and condition; Pelvic stenosis; Oligo Hydramnius; Road pair and decoy; Use of analgesia and oxytocin; The need for oxytocin to induce and accelerate labor; Creating any problem in the delivery process that requires midwifery interventions.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

A table of random numbers is used; If the numbers 1, 2, 3 are selected; the people are in group A (delivery ball) and the numbers 4, 5, 6 are in group B (walking) and the numbers 7, 8, 9 are in group C (Control group).

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 in Biomedical Research

Street address

Golestan Blv, Nursing And Midwifery Department

City

Ahvaz

Province

Khouzestan

Postal code

6135539345

Approval date

2020-05-12, 1399/02/23

Ethics committee reference number

IR.AJUMS.REC.1399.158

Health conditions studied

1

Description of health condition studied

labor pain intensity and duration of labor in primiparous mothers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intensity of labor pain

Timepoint

At the beginning of the study, dilation 6 cm, 8 cm, 10 cm

Method of measurement

VAZ

2

Description

Duration of labor pain

Timepoint

At the beginning of the study, dilation 6 cm, 8 cm, 10 cm

Method of measurement

Stopwatch

Secondary outcomes

empty

Intervention groups

1

Description

Walking. If the mother is in the walking group, she is asked to walk continuously or intermittently for at least 15 minutes per hour; At the beginning of the study, dilatation of 4 cm, 6 cm, 8 cm, and 10 cm is calculated using a WAZ ruler and McGill Pain Questionnaire and a stopwatch to assess the severity and duration of his pain.

Category

Treatment - Other

2

Description
Birth ball. If the mother is in the birth ball group, she is asked to sit on the ball continuously or intermittently for at least 15 minutes per hour; At the beginning of the study, dilatation of 4 cm, 6 cm, 8 cm, and 1 cm is calculated using the Waz ruler and McGill Pain Questionnaire and his stopwatch pain intensity and duration.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital of Ahvaz

Full name of responsible person
Samira Maleki

Street address
Golestan Boulevard

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6135539345

Phone
+98 61 3373 8333

Email
sam.maleki69@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Deputy of research and technology

Street address
Golestan Boulevard

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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
Private

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

Full name of responsible person
Samira Maleki

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Golestan Boulevard, Jundishapur University of Medical Sciences, School of Nursing and Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Nahid javadifar

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Demographic information of individuals and data before and after the intervention are reported without mentioning the name

When the data will become available and for how long

1400

To whom data/document is available

Researchers in the field of medical universities

Under which criteria data/document could be used

Can be used in similar research

From where data/document is obtainable

Researcher personal email

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

Due to the publication of the article and the registration of the responsible author's information, the applicant will contact the responsible author to receive the data information by academic email, and after confirming the academic email, the information will be sent

Comments