

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Oct 2026

A comparative study of the effects of birthing balls and hot showers on the intensity of pain during the active phase of labor in primiparous pregnant women.

Protocol summary

Study aim

The effect of hot water shower and birthing on the intensity of active labor pain in primiparous women

Design

On three cards marked with the letters C-A-B, where card A represents the birth ball group, card B represents the hot shower group, and card C represents the control group. The intervention consisted of 20 minutes of exercise with a birthing ball (sizes 55 and 65) at dilations of 4 cm, 6 cm, and 8 cm. After the intervention, the intensity of pain was measured at the three dilation times mentioned. In the second group, a hot shower with a temperature of 38-40 degrees was used for 20 minutes at the final dilations of 4 cm, 6 cm, and 8 cm, which lasted for one hour in total, and was performed on the lumbar and sacral areas. Routine maternity care is also used in the control group.

Settings and conduct

After receiving a written letter of introduction from Hamedan University of Medical Sciences and Malayer Faculty of Medical Sciences and obtaining permission from Mehr Malayer Hospital, the samples are initially included in the study based on meeting the research entry criteria and obtaining consent.

Participants/Inclusion and exclusion criteria

Primiparous women between the ages of 18-35, women in the beginning of the active phase of labor (3-4 cm dilation and uterine contractions for 30 seconds and 3 contractions in 10 minutes), gestational age 37-42 weeks, singleton fetus, breech presentation, absence of fetal heart disorder

Intervention groups

The intervention in the first group was 20 minutes of exercise with a birthing ball (sizes 55 and 65) at dilations of 4 cm, 6 cm, and 8 cm. In the second group, a hot shower with a temperature of 38-40 degrees was used in the lumbar and sacral region for 20 minutes at final

dilations of 4 cm, 6 cm, and 8 cm. Routine maternity care is also used in the control group.

Main outcome variables

The intensity of labor pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241110063652N2**

Registration date: **2025-03-26, 1404/01/06**

Registration timing: **registered_while_recruiting**

Last update: **2025-03-26, 1404/01/06**

Update count: **0**

Registration date

2025-03-26, 1404/01/06

Registrant information

Name

zahra kohzad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6523 5751

Email address

zk.kohzad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-16, 1403/11/28

Expected recruitment end date

2025-04-20, 1404/01/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effects of birthing balls and hot showers on the intensity of pain during the active phase of labor in primiparous pregnant women.

Public title
The effect of birthing balls and hot showers on the intensity of pain in the active phase of labor in pregnant women

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Primiparous women Women at the beginning of the active phase of labor Gestational age 37-42 weeks Singleton fetus Showing the embryo series
Exclusion criteria:
 Fetal heart defect Drug addiction Intrauterine growth restriction Diagnosed mental or anatomical disorder

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples are randomly assigned to three groups by a third party who is not involved in the research protocol. On three cards marked with the letters C-A-B, where card A represents the birthing ball group, card B represents the hot shower group, and card C represents the control group. The samples are randomly assigned to three groups .The first patient to enter the study is given three cards, chooses Wiki, and is placed in one of the groups. The second is given two cards and is placed in one of the groups, and finally the third is placed in the third group, and from then on the samples are randomly placed in the three groups.

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 Hamadan University of Medical Sciences

Street address

Central Headquarters of Hamadan University of Medical Sciences, Shahid Fahmideh Blvd.

City

Hamadan

Province

Hamadan

Postal code

6517838736

Approval date

2025-02-15, 1403/11/27

Ethics committee reference number

IR.UMSHA.REC.1403.833

Health conditions studied

1

Description of health condition studied

Delivery

ICD-10 code

O80

ICD-10 code description

Single spontaneous delivery

Primary outcomes

1

Description

Pain

Timepoint

At final dilatation of 4 cm, 6 cm and 8 cm

Method of measurement

Visual pain scale

Secondary outcomes

empty

Intervention groups

1

Description

20 minutes of hot water shower with a temperature of 38-40 degrees at final dilation of 4 cm, 6 cm and 8 cm, which is a total of one hour, and is performed in the lumbar and sacral area.

Category

Other

2

Description

Intervention group: 20 minutes of exercise with a birthing ball (sizes 55 and 65) at dilations of 4 cm, 6 cm, and 8 cm, for a total of one hour.

Category

Other

3

Description

Control group: Routine care in the delivery room

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr Malayer Hospital

Full name of responsible person

Zahra Kahzad

Street address

Opposite Melal Park, Above Nabuwwat Square

City

Malayer

Province

Hamadan

Postal code

65718-64953

Phone

+98 937 039 6712

Email

zk.kohzad@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Alireza Soltanian

Street address

5th Floor, Central Headquarters of Hamadan
University of Medical Sciences, Pajhohesh Square,
Shahid Fahmideh Blvd.

City

Hamadan

Province

Hamadan

Postal code

65178-38736

Phone

+98 81 3131 0000

Email

zk.kohzad@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Zahra Kohzad

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Hamedan University of Medical Sciences, Shahid
Fahmideh Boulevard, Pajhohesh Sq.

City

Hamedan

Province

Hamadan

Postal code

6517838736

Phone

+98 21 6523 5751

Email

zk.kohzad@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Phone
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Email
zk.kohzad@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Zahra Kohzad
Position
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Latest degree
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Other areas of specialty/work
Midwifery
Street address
Hamedan University of Medical Sciences, Shahid
Fahmideh Boulevard, Pajhohesh Sq.
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Province

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zk.kohzad@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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