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
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65718-64953
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+98 937 039 6712
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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.
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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
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
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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