Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Exercise program with the birth ball on duration of labor stages in nulliparous women

Protocol summary

Summary

This clinical trial has been designed to determine the effect of exercise programme with birth ball during pregnancy on duration of labor stages in nulliparous women. Study subjects are Iranian women 35-18 years old with term pregnancy, without history of infertility, singleton pregnancy who have Body mass index in normal range, and without any chronic illnesses or antenatal complications (low-risk pregnancies) in current pregnancy. After explaining aims of study and getting consent and confidence of gestational age, subjects will be randomly assigned to one of two groups: exercise program with the birth ball and usual care. After training by 20 minutes video film about exercise programme with the birth ball to intervention group, a birth ball, booklet and training CD will be given to mothers, and we will ask mothers to perform the exercise with help of trained attendant, three times a week at Home and once a week in the hospital setting for 20 minutes until onset of labor. usual care will be done for mothers in control group. Both groups will be asked to go to the hospital at the onset of labor and inform the researcher. The researcher will be present in Hospital and in absence of exclusion criteria during study, they will be controlled by researcher, at the end of active phase of labor and second stage of labor are compared in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012816392N1**
Registration date: **2014-06-15, 1393/03/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-06-15, 1393/03/25

Registrant information

Name
Zahra Hejazinia
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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hejaziniaz901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad Universityof Medical Sciences

Expected recruitment start date

2013-09-16, 1392/06/25

Expected recruitment end date

2014-03-17, 1392/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Exercise program with the birth ball on duration of labor stages in nulliparous women

Public title

The effect of Exercise program with the birth ball during pregnancy on duration of labor stages

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Iranian women who are living in Mashhad city; nulliparus or primiparous women; age 18

to 35 years old; pregnant women between 37-38 weeks; singleton pregnancy; BMI in the normal range; low-risk pregnancies; no Regular exercise during pregnancy. Exclusion criteria: not willingness to participate in research; not doing exercise program three times or more; emergency caesarean section; use of traditional, herbal medicines or other methods to facilitate delivery; smoking, alcohol consumption and substance abuse; induction of labor before 37 complete weeks.

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Mashhad Universityof Medical Sciences

Street address

Building Qureshi, Daneshgah Avenue, mashhad

City

Mashhad

Postal code

Approval date

2013-05-26, 1392/03/05

Ethics committee reference number

920056

Health conditions studied

1

Description of health condition studied

Pregnancy

ICD-10 code

Z37.0

ICD-10 code description

Single live birth

Primary outcomes

1

Description

Duration of the active phase of labor

Timepoint

End of study

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Duration of second stage of labor

Timepoint

End of study

Method of measurement

Questionnaire

Intervention groups

1

Description

After practical training and face to face and videotape(20 minutes) to intervention group and attendant person, was given to pregnant women a birth ball with booklet, 20-minute training video on CD with check list to ensure implementation of exercise program at home and was asked from mothers is performed this movement until onset of labor(from 34 weeks to term) with the help of attendant trained, three times a week at Home and once a week in the Hospital setting for 20 minutes.the subjects taught about symptoms of the onset of labor,and was requested them go to Hospital at onset of labor with informed to researcher .

Category

Other

2

Description

In control group,pregnant women were controlled weekly(from 34 weeks to term) until onset of labor.the subjects taught about symptoms of the onset of labor, and was requested them go to Hospital at onset of labor with informed to researcher .

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Omolbanin hospital
Full name of responsible person
Mirzakhani Kobra, MS Nursing, Midwifery Training
Street address
Omolbanin Women's Hospital (SA), Zarineh cross roads, Mashhad, Khorasan Razavi
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Research Mashhad University(Dr.tafaghodi)
Street address
Building Qureshi, University Avenue, Mashhad,Khorasan Razavi
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty