

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 4455 3314

###### Email address

hejaziniaz901@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Mashhad University of 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; nulliparous 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 willing 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 University of 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**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Kobra Mirzakhani

**Position**

Faculty member

**Other areas of specialty/work**

**Street address**

School of Nursing and Midwifery, Doktora crossroad,  
Mashhad, Khorasan Razavi

**City**

Mashhad

**Postal code**

**Phone**

+98 51 1859 1511

**Fax**

**Email**

mirzakhani@mums.ac.irhejazinia901@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Kobra Mirzakhani

**Position**

Master of Midwifery

**Other areas of specialty/work**

**Street address**

School of Nursing and Midwifery, Doktora crossroad,  
Mashhad, Khorasan Razavi

**City**

Mashhad

**Postal code**

**Phone**

+98 51 1859 1511

**Fax**

**Email**

mirzakhani@mums.ac.ir

**Web page address**

hejazinia901@mums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Zahra Hejazinia

**Position**

Midwife

**Other areas of specialty/work**

**Street address**

School of Nursing and Midwifery, Doktora crossroad,  
Mashhad, Khorasan Razavi

**City**

Mashhad

**Postal code**

**Phone**

+98 51 1859 1511

**Fax**

+98 51 1859 1511

**Email**

hejazinia901@mums.ac.ir

**Web page address**

## 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*