

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jun 2026

Effect of pelvic floor exercises versus no exercise on the need for episiotomy in nulliparous women: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of pelvic floor exercises versus no exercise on the need for episiotomy in nulliparous women. Design: A randomized clinical trial. Setting and conduct: The eligible nulliparous women who will refer to Fatemeh Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 20 to 40 years; nulliparous women; 20 weeks of gestational age; singleton pregnancy; educational level of secondary school or higher. Exclusion criteria: Emergency situation for delivery; abnormal placenta or vasa previa; professional athlete. Intervention group: Routine care during pregnancy plus pelvic floor exercises including rapid and slow contractive pelvic motion 20 to 30 min 3 times a week for 8 weeks. Control group: Just routine care during pregnancy. Primary outcome: The need for episiotomy during delivery based on physical examination. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709159014N185**
Registration date: **2017-09-22, 1396/06/31**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-22, 1396/06/31

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pelvic floor exercises versus no exercise on the need for episiotomy in nulliparous women: a randomized clinical trial

Public title

Effect of pelvic floor exercises versus no exercise on the need for episiotomy in nulliparous women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age of 20 to 40 years; nulliparous women; 20 weeks of gestational age; singleton pregnancy; educational level of secondary school or higher. Exclusion criteria: Emergency situation for delivery; abnormal placenta or vasa previa; professional

athlete.

Age

From **20 years** old to **40 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**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code**Approval date**

2010-08-20, 1389/05/29

Ethics committee reference number

IR.UMSHA.REC.1396.305

Health conditions studied**1****Description of health condition studied**

Episiotomy

ICD-10 code

O90.1

ICD-10 code description

Disruption of perineal obstetric wound

Primary outcomes**1****Description**

The need for episiotomy

Timepoint

during delivery

Method of measurement

based on physical examination

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Routine care during pregnancy plus pelvic floor exercises including rapid and slow contractive pelvic motion 20 to 30 min 3 times a week for 8 weeks.

Category

Treatment - Other

2**Description**

Control group: Just routine care during pregnancy.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Fatemieh Hospital

Full name of responsible person

Fetemeh Ghamari Mehran

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research and Technology, Hamadan 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

School of Nursing and Midwifery

Full name of responsible person

Fetemeh Ghamari Mehran

Position

Midwifery Student

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Postal code

Phone

+98 81 3838 0572

Fax

Email

alijavad738@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery

Full name of responsible person

Dr Seyyedh Zahra Masoomi

Position

Specialist in Fertility Hygiene

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Postal code

Phone

+98 81 3838 0572

Fax

Email

zahramid2003@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

Phone

+98 81 3838 0090

Fax

Email

poorolajal@umsha.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