

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Prophylactic effect of Kegel physical exercises and physiotherapy versus no intervention on the urinary incontinency and urinary urgency after normal delivery: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of prophylactic effect of Kegel physical exercises and physiotherapy versus no intervention on the urinary incontinence and urinary urgency after normal delivery

##### Design

This is a randomized clinical trial, phase II, in which 150 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible women with normal delivery who will refer to Fatemeh Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 35 years, Normal and term delivery, Singleton Exclusion criteria: Episiotomy, Gestational diabetes, Preeclampsia

##### Intervention groups

Intervention group 1: Routine postpartum care plus Kegel physical exercise 3 times a day every week for 6 weeks including pelvic floor contraction for 10 seconds and will be repeated for 15 to 20 times in supine, standing, and quadruped position Intervention group 2: Routine postpartum care plus physiotherapy of the pelvic floor muscle once a week for 6 weeks Control group: Just routine postpartum care

##### Main outcome variables

Primary outcome: Urinary incontinence and urinary urgency

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N326**

Registration date: **2019-12-27, 1398/10/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-27, 1398/10/06**

Update count: **0**

##### Registration date

2019-12-27, 1398/10/06

##### 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

##### Expected recruitment start date

2019-12-22, 1398/10/01

##### Expected recruitment end date

2020-12-21, 1399/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Prophylactic effect of Kegel physical exercises and

physiotherapy versus no intervention on the urinary incontinence and urinary urgency after normal delivery: a randomized clinical trial

#### Public title

Prophylactic effect of Kegel physical exercises and physiotherapy versus no intervention on the urinary incontinence and urinary urgency after normal delivery

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age of 18 to 35 years, Normal and term delivery, Singleton

##### Exclusion criteria:

Episiotomy, Gestational diabetes, Preeclampsia

#### 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: **150**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare three sheets and write "intervention 1" on one sheet and "intervention 2" on the other sheet and "control" on the third one. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

#### 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

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

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Approval date

2019-11-16, 1398/08/25

#### Ethics committee reference number

IR.UMSHA.REC.1398.646

## Health conditions studied

### 1

#### Description of health condition studied

Urinary incontinence

#### ICD-10 code

N39.3

#### ICD-10 code description

Stress incontinence (female) (male)

### 2

#### Description of health condition studied

Urinary urgency

#### ICD-10 code

R39.15

#### ICD-10 code description

Urgency of urination

## Primary outcomes

### 1

#### Description

Urinary incontinence and urinary urgency

#### Timepoint

6 weeks after the intervention

#### Method of measurement

By taking history

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Routine postpartum care plus Kegel physical exercise 3 times a day every week for 6 weeks including pelvic floor contraction for 10 seconds and will be repeated for 15 to 20 times in supine, standing, and quadruped position

#### Category

Prevention

### 2

#### Description

Intervention group 2: Routine postpartum care plus physiotherapy of the pelvic floor muscle once a week for 6 weeks

**Category**

Prevention

**3**

**Description**

Control group: Just routine postpartum care

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Fatemieh Hospital in Hamadan city

**Full name of responsible person**

Dr Mahsa Bakhtiar

**Street address**

Fatemieh Hospital, Pasdaran Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3828 3939

**Email**

mahsabahkhthari629189@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

info.research@umsha.ac.ir

**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**

Dr Mahsa Bakhtiar

**Position**

Resident of Gynecology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Fatemieh Hospital, Pasdaran Ave.

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**Postal code**

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**Phone**

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**Email**

mahsabahkhthari629189@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Mahsa Bakhtiar

**Position**

Resident of Gynecology

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**Email**

mahsabakhthari629189@gmail.com

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

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

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone****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