Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Fatemieh 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
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Iran (Islamic Republic of)
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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 incontinency 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

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6517838695

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mahsabakhthari629189@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Dr Mahsa Bakhtiar

Position

Resident of Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
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Professor of Epidemiology
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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