

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of the effect of Kegel exercise and Kegelmaster device on the urinary incontinence in women and a comparison between them

Protocol summary

Summary

The purpose of the present study is to evaluate the effect of Kegel exercise with and without Kegelmaster device on the urinary incontinence in women. Materials & method: A randomized clinical trial was performed on 91 women with the complaint of urinary incontinence who had the inclusion criteria. They were randomly assigned into the two groups. In the case group (n=41), after complete training, kegel master device were used twice daily and 15 minutes every session, for a total duration of 12 weeks. The control group (n= 50), after complete training, kegel exercises were done (including perineal muscles contractions for 6-8 seconds with 6 seconds rest in between), twice daily and 15 minutes every session, for a total duration of 12 weeks. Then these two groups were compared according to the scores of special questionnaires, before , 1 and 3 months after interventions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811252624N3**

Registration date: **2010-05-03, 1389/02/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-03, 1389/02/13

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, Deputy of Research and Technology

Expected recruitment start date

2009-01-01, 1387/10/12

Expected recruitment end date

2009-12-01, 1388/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Kegel exercise and Kegelmaster device on the urinary incontinence in women and a comparison between them

Public title

Effect of Kegel exercise and Kegelmaster device on the urinary incontinence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: stress urinary incontinence (SUI) and mixed urinary incontinence, reproductive age (before menopause) and normal urinalysis and negative urine culture. Exclusion criteria: pregnancy or post partum period (6 weeks after delivery), any drug use or surgery for UI, any urogenital infection, any systemic disorders or drug use, including chronic degenerative disorders, neuromuscular disorders, rapid progressive pelvic

prolapsus, cardiac pacemaker, and other forms of UI.

Age

From **25 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **38**

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

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences

City

Tehran

Postal code

Approval date

2009-03-01, 1387/12/11

Ethics committee reference number

1182874

Health conditions studied

1

Description of health condition studied

urinary incontinence in women

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence

2

Description of health condition studied

Other specified urinary incontinence

ICD-10 code

N39.4

ICD-10 code description

Other specified urinary incontinence

Primary outcomes

1

Description

quality of life

Timepoint

1 and 3 months after interventions

Method of measurement

questionnaires

2

Description

strength of pelvic floor muscles

Timepoint

1 and 3 months after interventions

Method of measurement

Oxford grading system

3

Description

capability to participate in the social activities

Timepoint

1 and 3 months after interventions

Method of measurement

Questionnaire

4

Description

number of involuntary urine passage

Timepoint

1 and 3 months after interventions

Method of measurement

questionnaire

5

Description

severity of urinary incontinence

Timepoint

1 and 3 months after interventions

Method of measurement

Visual Analogue Scoring (VAS),

Secondary outcomes

empty

Intervention groups

1

Description

Kegelmaster devise

Category

Treatment - Devices

2

Description

Kegel exercises

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Teaching Hospital

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

12 Bahban Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences, Deputy of
Research and Technology

Full name of responsible person

Dr Motavallian

Street address

Iran University of Medical Sciences, Deputy of
Research and Tech

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences, Deputy of Research
and Technology

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

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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