Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effect of Kegel excersise and Kegelmaster devise 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 excersise with and without Kegelmaster devise 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 devise 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 excersise and Kegelmaster devise on the urinary incontinence in women and a comparison between them

Public title

Effect of Kegel excersise and Kegelmaster devise 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

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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