Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing The Effect of Heavy Lifting on Lower Urinary Tract System in Patients with Urinary Incontinence and Healthy Women Using Biomechanical and Urodynamic Study

Protocol summary

Summary

(1) Objectives, The aim of this clinical trial is to compare the effect of heavy lifting on the lower urinary tract system in patients with urinary incontinence and healthy women using biomechanical and urodynamic studies. (2) Design, A single center study will be conducted enrolling 50 participants. (Each group consisting of 25 participants). Blinding is not possible for patients but the performer and assessor will be blind to the history of underlying incontinence. (3) Setting,conduct and Interventions: The setting is urodynamic center of Imam Reza Hospital, Tabriz, Iran.Modeling of lifting heavy weights and holding them using a simulator device will be used to understand the changes in intra-abdominal pressure, intra-vesical pressure and the pressure of detrusor with empty and full bladder, with anal and vesical sensors while running urodynamic study. Maximum Voluntary Contraction (MVC) of participants with full or empty bladder will be measured simultaneosly with urodynamic study and leakage will be recorded if happened. (4) Participants, Fifty participants ranging 30 to 65 years will be enrolled in the study. incontinence group will contain participants with urinary incontinence diagnosed according to urological guidelines and healthy group will consist of participants with no complain about voiding symptoms. (5) main outcome measures, Involuntary leakage threshold, Maximum Voluntary Contraction (MVC),the changes in intra-abdominal pressure, intra-vesical pressure, also pressure of detrusor, while lifting heavy weight with empty and full bladder will be assessed in incontinent and healthy women.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020812728N3**
Registration date: **2017-08-18, 1396/05/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-18, 1396/05/27

Registrant information

Name

Sakineh Hajebrahimi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Office of the Vice Chancellor for Research of Tabriz University of Medical Sciences, Iranian Evidence Based Medicine Center of Excellence

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-07-20, 1396/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing The Effect of Heavy Lifting on Lower Urinary Tract System in Patients with Urinary Incontinence and Healthy Women Using Biomechanical and Urodynamic Study

Public title
The Effect of Heavy Lifting on The Dynamic of Lower Urinary Tract System
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria for this study is women with the age of 30 to 65; and the inclusion criteria for incontinence group is women who have confirmed diagnosis of urinary incontinence according to urological guidelines .
Exclusion criteria: being professional athlete; Diabetes; Hypertension; History of any skeletal problem; post operative; Neurological and Cardiovascular diseases; BMI over 39; Urinary Tract Infections; no consent for participating in the trial.
Age
From **30 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double 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 Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Attar Neyshabouri Street, Tabriz, Iran
City
Tabriz
Postal code
Approval date
2017-01-09, 1395/10/20
Ethics committee reference number
IR.TBZMED.REC.1395.1051

Health conditions studied

1

Description of health condition studied
Urinary Incontinence
ICD-10 code
N39.3
ICD-10 code description
Stress Incontinence

Primary outcomes

1

Description
Urinary leakage threshold
Timepoint
During intervention
Method of measurement
Obsevration and Urodynamical Study

2

Description
Maximum Voluntary Contraction (MVC)
Timepoint
During intervention
Method of measurement
Bio-dynamic Simulator

3

Description
Abdominal, Vesical and detrusor pressures
Timepoint
Before and during intervention
Method of measurement
Urodynamical Study

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Simulating holding heavy weight in healthy women - The designed device will evaluate and record forces of participants during lifting process synchronized with urodynamic device. Using Lab view software data with frequency of 10 data per second will be recorded in the system.
Category
Other

2

Description
Intervention group: Simulating holding heavy weight in incontinent women - The designed device will evaluate and record forces of participants during lifting process synchronized with urodynamic device. Using Lab view software data with frequency of 10 data per second will be recorded in the system.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Urodynamic center, Imam reza hospital
Full name of responsible person
Prof. Sakineh Hajebrahimi
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First floor, Urodynamic center, Imam Reza Hospital, Golgasht Street, Tabriz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Office of the Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences
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Prof. Mohammadreza Rashidi
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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
Office of the Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Iranian Evidence Based Medicine Center of excellence
Full name of responsible person
Prof. Sakineh Hajebrahimi
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Iranian Evidence based Medicine Center, Faculty of Medicine,Tabriz University of Medical Sciences, Attar Neyshabouri Street, Tabriz, Iran
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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
Iranian Evidence Based Medicine Center of excellence
Proportion provided by this source
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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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