

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 simultaneously 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

Urology Department, Tabriz University of Medical Sciences

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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

Street address

First floor, Urodynamic center, Imam Reza Hospital, Golgasht Street, Tabriz, Iran

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Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Office of the Vice Chancellor for Research (VCR) of Tabriz University of Medical Sciences

Full name of responsible person

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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Tabriz

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

Urology Department, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mona Mohiti Asli

Position

Resident of Urology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Professor of Urology- Fellowship in Female Urology

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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