

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Investigating the effect of magnetic therapy on the improvement of stress urinary incontinency in obese women referred to Ghadir mother and child hospital

Protocol summary

Study aim

The Effect of Magnet Therapy on Improving Stress Urinary Incontinence in Obese Women

Design

A randomized, controlled, single blinded clinical trial

Settings and conduct

In this clinical trial study, 22 obese women with stress urinary incontinence were randomly divided into two groups. 11 in control group and 11 in intervention group. patients do only special exercises in control group and patients also received magnet therapy in other group. Both of groups evaluated at the beginning of study, at the end of 8th session and one month after last session. A person out of study evaluated patients in blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women over 21 years with similar number of deliveries with stress urinary incontinence. Body mass index in the range of 30-35. Lack of neurological diseases. Lack of sensory and motor disorders. No mental illness. No muscular and articular disease. Urinary leakage during cough. Urinary incontinence and quality of life questionnaire score of at least study voluntarily and by signing the consent form. Exclusion criteria: other types of urinary incontinence such as urgent urinary incontinence. History of any heart failure. Pacemaker and metal in body. Acute infection. Malignancy. Pregnancy or pregnancy attempts. Surgery to treat stress urinary incontinence. Vaginal bleeding. History of pelvic surgery between 3-8 weeks ago. History of pelvic radiation. ulcers or burns in the pelvic area. History of medication for urinary incontinence in the last three months. High blood sugar above 100mmol / lit 14.

Intervention groups

Group 1: Magnet therapy and pelvic floor exercises.
Group 2: Pelvic floor exercises only.

Main outcome variables

The quality of life questionnaire related to urinary

incontinence, the number of pads used and the amount of urine leakage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190909044734N2**

Registration date: **2020-03-21, 1399/01/02**

Registration timing: **retrospective**

Last update: **2020-03-21, 1399/01/02**

Update count: **0**

Registration date

2020-03-21, 1399/01/02

Registrant information

Name

Leila Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

leabbasi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

2019-04-21, 1398/02/01

Actual recruitment end date

2019-07-22, 1398/04/31
Trial completion date
 2019-10-22, 1398/07/30

Scientific title
 Investigating the effect of magnetic therapy on the improvement of stress urinary incontinence in obese women referred to Ghadir mother and child hospital

Public title
 The effect of magnet therapy on the improvement of urinary incontinence

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Women 21 years and older with similar number of deliveries with stress urinary incontinence Body mass index in the range of 30-35 Lack of neurological diseases such as multiple sclerosis. Lack of sensory and motor disorders. Lack of mental illnesses (preventing proper communication and understanding) no musculoskeletal disorders. presence of urine leakage during coughing urine leakage of about 200-250 ml. incontinence questionnaire score Urine and quality of life should be at least 6 (normal is 21). Ability to perform pad test The patient should participate in the study voluntarily and by signing the consent form.
Exclusion criteria:
 People with other types of urinary incontinence such as urgent urinary incontinence, functional urinary incontinence, mixed urinary incontinence. History of any heart failure and illness such as severe cardiac arrhythmia hypertension. Pacemaker and metal In the body Acute infection Malignancy Pregnancy or try for pregnancy Surgery to treat stress urinary incontinence. Vaginal bleeding History of pelvic surgery between 3-8 weeks ago History of pelvic radiation Having Pelvic ulcer or burn. History of medication for urinary incontinence in the past three months such as alpha-adrenergic, diuretic, serotonin, epinephrine. High blood sugar glucose 100mmol / lit

Age
 From **21 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked

- Data analyser
- Data and Safety Monitoring Board

Sample size
 Target sample size: **24**
 Actual sample size reached: **22**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Volunteer patients were randomly assigned to one of two intervention or control groups with blocked randomization method. six blocks with the size of four were considered and 12 subjects were placed in each

group.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 Patients were aware of the second group at the time of filling out the informed consent form and were therefore not blind to the groups. The therapists were also aware of both groups and types of treatment, and the just the person who evaluate the patients was completely blind to the groups and treatment received, and the data were also analyzed by someone who was completely blind.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of research of Shiraz Faculty of Rehabilitation Sciences
Street address
 Abyvardi 1 Street. Chamran Blvd.
City
 shiraz
Province
 Fars
Postal code
 1733-71345

Approval date
 2019-04-17, 1398/01/28

Ethics committee reference number
 IR.SUMS.REHAB.REC.1398.002

Health conditions studied

1

Description of health condition studied
 Pelvic floor disorder

ICD-10 code
 N39.3

ICD-10 code description
 Stress incontinence (female) (male)

Primary outcomes

1

Description
 The quality of life questionnaire,

Timepoint
 Before the intervention and treatment of the eighth session and one month after the last treatment session

Method of measurement

I-QOL questionnaire

2

Description

urinary incontinence intensity,

Timepoint

Before the intervention and treatment of the eighth session and one month after the last treatment session

Method of measurement

By determining the amount of urine absorbed in the pad

3

Description

urinary incontinence frequency,

Timepoint

Before the intervention and treatment of the eighth session and one month after the last treatment session

Method of measurement

Using the patient self report

4

Description

urine frequency,

Timepoint

Before the intervention and treatment of the eighth session and one month after the last treatment session

Method of measurement

Using the patient self report

5

Description

delivery frequency,

Timepoint

Before the intervention and treatment of the eighth session and one month after the last treatment session

Method of measurement

Using the patient self report

6

Description

BMI

Timepoint

Before the intervention and treatment of the eighth session and one month after the last treatment session

Method of measurement

using BMI index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They received magnet therapy and

pelvic floor exercises

Category

Rehabilitation

2

Description

Control group: They only received pelvic floor exercises

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz School of Rehabilitation

Full name of responsible person

Leila Abbasi

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Abiverdi 1 street, Chamran Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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Zand Street, opposite Palestine Street, Central Building of Shiraz University of Medical Sciences, research vice-chancellor

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ghasemiy@sums.ac.ir

Web page address

http://research.sums.ac.ir/fa/vice_chancellor_introdu

ion/vice-chancellor.html

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Leila Abbasi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available