

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Investigation the laser acupuncture effect on some clinical parameters of female patients with overactive bladder syndrome.

Protocol summary

Summary

(1) Objectives: The aim of the present study is investigation the effect of laser acupuncture on some clinical parameters, quality of life and depression of female patients with overactive bladder syndrome. (2) Design: This is a single blinded randomized clinical trial. The patients will not aware about grouping. (3) Setting and conduct: a) filling the informed consent and general information forms. The quality of life and depression questionnaires will fill, too. b) Recording the variables of the present study for 3 days by the patients before starting the study. c) Grouping the patients randomly to control and intervention groups, each included 25 patients. d) Execution the physiotherapy protocol for both groups. e) Filling the quality of life and depression questionnaires at the end of the physiotherapy program. f) Comparing before and after physiotherapy program results. 4) Participants: 30 to 60 years old female patients with overactive bladder syndrome. Most important inclusion criteria: female patients with urinary incontinence; urinary urgency for at least 2 times per 3 days; waking up for urination at least one time at night; urinary frequency at least 8 times per day. Most important exclusion criteria: any other treatment for overactive bladder along with present study; unable to record bladder diary; lower urinary tract infection. (5) Intervention: For intervention group physiotherapy program will be pulsed low level laser radiation with 810 nm wavelength on suggested acupuncture points with energy density of 4 joules/cm² for 40 seconds/each point. Controlled group will receive sham laser on the same points. Treatment sessions will last 4 weeks, each week included 2 sessions. For consideration of ethics, a complete physiotherapy program included pelvic floor exercise will start for both groups after finishing the study. (6) Variables: Urinary incontinence; frequent urination; urinary urgency; nocturia and also the sf-36 quality of life and beck depression questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015022118754N3**

Registration date: **2015-09-13, 1394/06/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-13, 1394/06/22

Registrant information

Name

Javad Sarrafzadeh

Name of organization / entity

Iran University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the laser acupuncture effect on some clinical parameters of female patients with overactive bladder syndrome.

Public title

Investigation the Laser acupuncture effect in treatment of overactive bladder syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female patients with urinary incontinence; urinary urgency for at least 2 times per 3 days; waking up for urination at least one time at night; urinary frequency at least 8 times per day. Exclusion criteria: any other treatment for over active bladder along with present study; unable to ambulate; unable to record bladder diary; lower urinary tract infection; epilepsy; infection at laser acupuncture points; pregnancy; background of radiotherapy and incomplete physiotherapy program of the research.

Age

From **30 years** old to **60 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Iran University of Medical Sciences

Street address

5th floor, Iran University of Medical Sciences, Hemmat highway

City

Tehran

Postal code

Approval date

2014-06-15, 1393/03/25

Ethics committee reference number

105/1275/93/3

Health conditions studied

1

Description of health condition studied

Overactive bladder syndrome

ICD-10 code

32.8

ICD-10 code description

Other specified urinary incontinence

Primary outcomes

1

Description

Urinary incontinence

Timepoint

Before starting the treatment and at the end of each treatment week

Method of measurement

The number of involuntary urine loss during the last 3 days of each treatment week based on bladder diary.

2

Description

Frequent urination

Timepoint

Before starting the treatment and at the end of each treatment week

Method of measurement

Bladder diary for the last 3 days of each treatment week.

3

Description

Nocturia

Timepoint

Before starting the treatment and at the end of each treatment week

Method of measurement

The number of waking up at night for urination based on bladder diary for the last 3 days of each treatment week.

4

Description

Urine urgency

Timepoint

Before starting the treatment and at the end of each treatment week

Method of measurement

The number of urinary urgency based on bladder diary for the last 3 days of each treatment week.

5

Description

Quality of life

Timepoint

Before and after treatment

Method of measurement

SF_36 questionnaire

6

Description

Depression

Timepoint

Before and after treatment

Method of measurement

Beck depression inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: an 810 nm pulsed low level laser radiation will use on acupuncture points related to overactive bladder syndrome with 4 joules per square centimeter for each point.

Category

Rehabilitation

2

Description

Placebo-controlled group: Sham pulsed low level laser on acupuncture points related to overactivity bladder syndrome.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical therapy clinic of rehabilitation school of Iran university of medical science

Full name of responsible person

Javad Sarrafzadeh

Street address

Physiotherapy Clinic of School of Rehabilitation Sciences, Madadkaran st., Shahnazari st, Mirdamad st., Tehran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Seyed Ali Javad Moosavi, Vice chancellor for research

Street address

5th Floor, Iran University of Medical Sciences, Hemmat highway

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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, Vice chancellor for research

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

School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

Javad Sarrafzadeh

Position

PT, PhD in Physiotherapy, Associated Professor

Other areas of specialty/work

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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