Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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 activebladder 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/د

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 quastionnaire

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