

# 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/cm<sup>2</sup> 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)

##### Phone

00982122228051-00982122227124

##### Email address

sarrafzadeh.j@iums.ac.ir

##### 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

Tehran

## 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

##### City

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

##### Street address

Physiotherapy department, School of Rehabilitation Sciences, Madadkaran st., Shahnazari st, Mirdamad St

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##### Web page address

<http://rehab.iums.ac.ir>

## Person responsible for scientific

## **inquiries**

### **Contact**

#### **Name of organization / entity**

School of Rehabilitation Sciences, Iran University of Medical Sciences.

#### **Full name of responsible person**

Javad Sarrafzadeh

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## **Person responsible for updating data**

### **Contact**

#### **Name of organization / entity**

Dept. of Physical therapy, School of Rehabilitation Sciences, Iran University of Medical Sciences.

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### **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*