

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

A Clinical trial to compare the effect of CO2 laser and biofeedback therapy on quality of life in patients with overactive bladder syndrome.

Protocol summary

Summary

This study aimed to compare the effect of laser with common treatment of biofeedback therapy in patients with Overactive bladder syndrome (Urgency incontinence which is often associated with frequent urination in day and night). In this clinical trial, 60 patients with pelvic floor disorders referred to clinic of Imam Khomeini hospital in the year of 2016 were included. The inclusion criteria were Age more than 50 years, clinical diagnostic for overactive bladder, urgency and mixed urgency and Exclusion criteria were diabetes, the BMI more than 30 and not to use any previous treatments. The patients were randomly divided in to Laser and Biofeedback treatment groups. Thirty pockets for the laser and 30 pockets for the biofeedback group were assigned for randomization and patients drew out one card and were assigned to the groups according to the name written on the card. This process continued until the desired sample size was reached. The patients in the laser group (n=30) were treated with fractional laser CO2 during three sessions with one-month interval. The intervention for biofeedback group was pelvic exercise and assessment of the feedback in pelvis, twice a week lasting for 4 weeks. One month after treatment, the quality of life; the chart of three-day urinary symptoms and urinary symptoms were re-evaluated by the questionnaires in patients. The urinary urgency and frequency were the primary outcomes and the quality of life was the secondary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052127998N1**

Registration date: **2017-04-04, 1396/01/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-04, 1396/01/15

Registrant information

Name

Maryam Hajihashemi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 6578

Email address

m_hajihashemy@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tehran University of Medical Sciences.

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial to compare the effect of CO2 laser and biofeedback therapy on quality of life in patients with overactive bladder syndrome.

Public title

Comparison of the treatment effects with laser and biofeedback on overactive bladder syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age more than 50 years; presence of clinical diagnosis for overactive bladder; urgent or mixed incontinence; frequency of urination more than 8 times during the day; urination more than once at night.

Exclusion Criteria: absence of patient satisfaction; use of the other treatment during past 3 months; stage 3 or 4 of pelvic floor prolapse; vaginal lesions; use of previous Isoteritinoic; abnormal Pap smear; Diabetes; BMI more than 30.

Age

From **50 years** old to **75 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Tehran University of Medical Sciences

Street address

Central Building of Tehran University of Medical sciences, Ghods Street

City

Tehran

Postal code

14194

Approval date

2016-12-21, 1395/10/01

Ethics committee reference number

IR.TUMS.IKHC.REC.1395.1672

Health conditions studied

1

Description of health condition studied

Overactive Bladder Syndrome

ICD-10 code

N32.8

ICD-10 code description

Other specified disorders of bladder

Primary outcomes

1

Description

Urinary frequency

Timepoint

one month after treatment

Method of measurement

Questionnaire

2

Description

Urge incontinence

Timepoint

one month after treatment

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Quality of Life

Timepoint

one month after treatment

Method of measurement

The quality of Life Questionnaire

Intervention groups

1

Description

Intervention group1: The patients in the laser group were treated with fractional CO2 laser during three sessions with one-month interval between each two sessions.

Category

Treatment - Drugs

2

Description

Intervention group2: Patients in the biofeedback group were treated twice a week, for 4 weeks. The intervention in this group was pelvic exercise and observing pelvic feedback.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Pelvic Clinic

Full name of responsible person

Dr.Maryam Hajhashemy

Street address

Valiasr Pelvic Clinic, Imam Khomeini Hospital,
Keshavarz Blvd.

City

Tehran

Street address

Fifth floor,Valiasr Hospital number1,Imam Khomeini
Hospital,Keshavarz Blvd.

City

Tehran

Postal code

14194

Phone

+98 21 6658 1616

Fax

+98 21 6658 1658

Email

hajhashemy73@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of
Medical Sciences

Full name of responsible person

Dr.Masoud Younesian

Street address

Deputy of research and technolog, Floor N.6, Central
Bulding of Tehran University of Medical Sciences,
Ghods Street.

City

Tehran

Grant name

32818-30-03-95 کد پژوهشیار

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Tehran University of
Medical Sciences

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

Pelvic Clinic of Valiasr Hospital

Full name of responsible person

Dr.Maryam Hajhashemy

Position

Pelvic Flowship

Other areas of specialty/work

Person responsible for scientific inquiries

Contact

Name of organization / entity

Reproductive Health Research Center

Full name of responsible person

Dr.Zinat Ghanbari

Position

Professor

Other areas of specialty/work**Street address**

First floor,Valiasr Hospital 2,Imam Khomeini
Hospital,Keshavarz Blvd

City

Tehran

Postal code

14194

Phone

+98 21 6658 1616

Fax

+98 21 6658 1658

Email

drz_ghanbari@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Vali Asr Reproductive Health Research Center

Full name of responsible person

Fedyeh Haghollahi

Position

Researcher

Other areas of specialty/work**Street address**

First floor,Valiasr Hospital 2,Imam Khomeini
Hospital,Keshavarz Blvd.

City

Tehran

Postal code

14194

Phone

+98 21 6658 1616

Fax

+98 21 6658 1658

Email

fedyeh_hagh@yahoo.com

Web page address**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