

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of acupuncture stimulation on hip and bladder pelvic floor muscle in women with urinary incontinence in the age range of 40-75 years and its effects on urine volume

Protocol summary

Study aim

Investigating the role of electroacupuncture in the improvement of patients with non-stress incontinence

Design

This study is a randomized clinical trial. Patients with confirmed urinary incontinence are examined. The samples are randomly divided into two groups of intervention and control. By reviewing the literature and according to the studies carried out taking into account the ability of 80% and A significant 5% and Effect size of 7% and a drop of 10% of the sample jig are determined in each group of 38. The intervention will be performed using sterile acupuncture needles of 30x75, as well as an electroacupuncture device. The control group will also receive sham acupuncture in addition to pelvic floor exercises by sticking the needles in the mercuric points on the skin, and other components The intervention will be similar to the intervention group.

Settings and conduct

This study is a randomized clinical trial conducted between Sina Hospital and the Urology Center of Sina Hospital.

Participants/Inclusion and exclusion criteria

1-patients with confirmed stress-incontinence are included in the study 2-patients with non-stress incontinence are excluded from the study 3-Women with cardiovascular disease, pelvic orthopedic palsy, sensory neural disorders, pelvic neoplasms or pelvic diseases, bleeding ulcers, and anticoagulant drugs are not expected to be included in the study.

Intervention groups

The intervention will be performed using sterile needles of acupuncture size of 30 to 75, as well as an electroacupuncture device.

Main outcome variables

Time for urinating insomnia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131218015841N3**

Registration date: **2018-07-31, 1397/05/09**

Registration timing: **prospective**

Last update: **2018-07-31, 1397/05/09**

Update count: **0**

Registration date

2018-07-31, 1397/05/09

Registrant information

Name

Gholamreza Pourmand

Name of organization / entity

Urology Research Center, Tehran University of Medical Sciences, Tehran, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2019-08-06, 1398/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acupuncture stimulation on hip and bladder pelvic floor muscle in women with urinary incontinence in the age range of 40-75 years and its effects on urine volume

Public title

Evaluation of electroacupuncture in patients with stress urinary incontinence.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with confirmed stress-incontinence are included in the study

Exclusion criteria:

patients with non-stress incontinence are excluded from the study

Age

From **40 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

More than 1 sample in each individual

Number of samples in each individual: **18**

3 times a week for 6 months

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice-Chancellor in research affairs-Tehran University of Medical Sciences

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Quds Street

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1136746911

Approval date

2018-06-20, 1397/03/30

Ethics committee reference number

IR.TUMS.VCR.REC.1397.179

Health conditions studied**1****Description of health condition studied**

NON-stress incontinence

ICD-10 code

N99-N99

ICD-10 code description

Other disorders of the genitourinary system

Primary outcomes**1****Description**

Pad test

Timepoint

Before and after 6 weeks

Method of measurement

Scales with accurate to 0.001

2**Description**

Check the amount of urine tract

Timepoint

First and after 6 weeks

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Using sterile acupuncture needles in size of 30 to 75, as well as an electroacupuncture device. The needles will be inserted in the double-sided BL33 points (at the third pierced sacral) at a 30 to 45 degree angle and BL35 at a distance of 10 mm from the end of the coccyx, and some in the posterolateral path. After the needles are drawn, some will be manipulated until the person feels de qi (sense of needle, limb, limb, or other senses). The electrodes of the device are then attached to the needles and the electrical waves will be fed at 50 Hz and amplified from 1 to 5 ampoleides for 30 minutes. This intervention will take 3 sessions a week for 6 weeks. The intervention group, in addition to the

electro-echo pumpkin, will perform three sessions per week on separate days with pelvic floor booster exercises with 3 sets of 10 repetitions of Kegel exercise on separate days from the eco-pumpkin.

Category

Treatment - Other

2

Description

Control group: In addition to pelvic floor exercise, Sham acupuncture will be received by sticking the needles in the mercurial points on the skin, and other intervention components will be similar to the intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital, Urology Research Center

Full name of responsible person

Dr.Maryam Abolhasani

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Hassan-abad Sq.Emam Khomeini St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Tehran, Keshavarz Blvd,Quds Street,Central Building of Tehran University of Medical Sciences, Sixth Floor

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr.Maryam Abolhasani

Position

faculty memberE

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr.Gholamreza Pourmand

Position

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Latest degree

Subspecialist

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Associate

Latest degree

Bachelor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments