Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 acupuncyure 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)

Phone
+98 21 6634 8560

Email address
pourmand@tums.ac.ir

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 incontinency.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patiens with confirmed stress-incontinence are inclluded in the study
Exclusion criteria:
patiens 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
Street address
Quds Street
City
Tehran
Province
Tehran
Postal code
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 acupuncyure 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

Street address
Hassan-abad Sq.Emam Khomeini St

City
Tehran

Province
Tehran

Postal code
1136746911

Phone
+98 21 6634 8561

Fax
+98 21 6634 8560

Email
dr_m_abolhasani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
dr.mohammadali Sahraian

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

City
Tehran

Province
Tehran

Postal code
1124344674

Phone
+98 21 8163 3627

Email
www.sahraian@yahoo.com

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

Street address
Hanan Abad Sq,Emam Khomeini St

City
Tehran

Province
Tehran

Postal code
1136746911

Phone
+98 21 6634 8560

Email
dr_m_abolhasani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr.Gholamreza Pourmand

Position
faculty member

Latest degree
Subspecialist

Other areas of specialty/work
Urology

Street address
Hasan Abad Sq,Emam Khomeini St

City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8560
Email
gh_pourmand@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Farzaneh bagherpour
Position
Associate
Latest degree
Bachelor
Other areas of specialty/work
Laboratory Medicine
Street address
Hasan Abad Sq,Emam Khomeini St
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8560
Email
farzaneh.bagherpoor@yahoo.com

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