Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the Efficacy of Cupping Method on Urinary Incontinence in Women: A Randomized Clinical Trial

Protocol summary

Study aim

Evaluating the efficacy of Hot Cupping Method, on signs and symptoms and quality of life of Female Urinary Incontinence according to International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) and Incontinence Quality of Life (I-QOL) questionnaires compared to Tolterodine

Design

Randomized clinical trial; Randomized simple method has been done. Not blind, parallel group randomized trial. 30-70 old women with urge or mixed urinary incontinence are allocated into control and intervention groups. Each group having 38 subjects.

Settings and conduct

Samples are selected from Farhangian Clinic and Pelvic Floor Disorders Clinic of Imam Khomeini Hospital. They are allocated into two groups whit Simple Randomization Method, treated with Static Hot Dry Cupping and drug therapy with Tolterodine 2 mg.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 30-70 old women with Urge or mixed urinary incontinence; Being symptomatic for at least 3 months; not been treated for at least 2 week before study. Exclusion criteria: Acute or Recurrent Urinary Tract Infection; pregnancy or lack of contraception; chronic degenerative neuromuscular disease; Bladder cancer or previous record of it; pain of bladder or painful urine voiding; record of pelvic surgery during past one year; Excessive Weight Loss; Uncontrolled diabetes.

Intervention groups

Intervention group is treated with Static Hot Dry Cupping, The area of set cups is navel to pubic area; twice a week, Intervention time is 6 weeks. Control group: patients will receive one tablet of 2 mg of tolterodine, twice a day, Intervention time is 6 weeks. Results will be evaluated on weeks 3 and 6 and one month after the end of intervention.

Main outcome variables

evaluating of frequency, time and the amount of urine leakage and quality of life after treatment using ICIQ-SF and I-QOL questionnaires

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190527043729N2**
Registration date: **2021-11-21, 1400/08/30**
Registration timing: **prospective**

Last update: **2021-11-21, 1400/08/30**
Update count: **0**

Registration date

2021-11-21, 1400/08/30

Registrant information

Name
leila ghanbaryan
Name of organization / entity
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Iran (Islamic Republic of)
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+98 61 5283 2978
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the Efficacy of Cupping Method on Urinary Incontinence in Women: A Randomized Clinical Trial

Public title
"Effect of Cupping Method in treatment of Urinary incontinence"

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
30-70 Old Women with Urge or Mixed urinary lincontinence; Being symptomatic for at least 3 months; Not been treated for at least 2 week before study
Exclusion criteria:
Acute or Recurrent Urinary Tract Infection Pregnancy or Lack of Contraception Chronic Degenerative Neuromuscular Disease Bladder Cancer or previous record of it Pain of Bladder or Painful Urine Voiding Record of Pelvic Surgery during past one year Excessive Weight Loss Uncontrolled Diabetes

Age
From **30 years** old to **70 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
76 Women with Urge or Mixed Urinary Incontinence referred to Farhagyan Clinic, Behbahan University of Medical Sciences and Pelvic Floor Clinic of Imam Khomeini Hospital belongs to Tehran University of Medical Sciences, During the year 1400 are available to study and each person is randomly assigned to one of two groups. The randomization method is simple and individual randomization unit. The tool used in randomization is Excel software.

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
13 Floor, A Block, Headquarters of the Ministry of Health and Medical Education, Simayeiran Street, Between South Flamak and Zar Afshan Street, Qods Town, Tehran
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Province
Tehran
Postal code
1467664961

Approval date
2020-06-29, 1399/04/09

Ethics committee reference number
IR.TUMS.VCR.REC.1399.542

Health conditions studied

1

Description of health condition studied
Urge Incontinence

ICD-10 code
N39.41

ICD-10 code description
Urge incontinence

2

Description of health condition studied
Mixed Incontinence

ICD-10 code
N39.46

ICD-10 code description
Mixed incontinence

Primary outcomes

1

Description
Frequency of urinary leakage

Timepoint
At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention

Method of measurement
International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

2

Description
The amount of urine leakage

Timepoint
At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention

Method of measurement

International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

3

Description
Time leakage: leakage befor sleep
Timepoint
At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention
Method of measurement
International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

4

Description
Time of leakage: leakage before reaching the bathroom
Timepoint
At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention
Method of measurement
International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

5

Description
Time leakage: leakage of urine with coughing and sneezing
Timepoint
At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention
Method of measurement
International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

6

Description
The leakage of urine: leakage of urine with exercise
Timepoint
At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention
Method of measurement
International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

7

Description
The leakage of urine: urine leakage after urination immediately prior to wearing underwear
Timepoint
At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention
Method of measurement
International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form (ICIQ-SF) questionnaire

8

Description
Assessment of changes in quality of life
Timepoint
At the beginning of the intervention, after 3 and 6 weeks, 1 month after end of intervention
Method of measurement
Incontinence Quality of Life (I-QOL) questionnaire

Secondary outcomes

1

Description
presumptive skin complications
Timepoint
3 weeks after research start and 6 weeks after that (end of intervention)
Method of measurement
Measurement form of drug complications According to Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0

Intervention groups

1

Description
Intervention group is treated with Static Hot Dry Cupping, With flaming alcohol cotton, a vacuum is created in each cup so that the cup sticks to the skin. The skin should protrude 2 to 3 cm into the cup. The cups are 45 mm in diameter. 4 to 6 cups, depending on the size of the person, are placed in two rows from below the navel to the pubic area and are kept for twenty minutes, twice a week, for 6 weeks.
Category
Treatment - Devices

2

Description
Control group: patients will receive one tablet of 2 mg of tolterodine, Produced by Tehran Daru Pharmaceutical Company, twice a day, Intervention time is 6 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farhangian Clinic, Behbahan University of Medical Sciences
Full name of responsible person
Leila Ghanbaryan
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2

Recruitment center
Name of recruitment center
Pelvic Floor Clinic of Imam Khomeini Hospital belongs to Tehran University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
http://vcr.tums.ac.ir
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
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Position
PhD candidate of Traditional Medicine
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the main and secondary consequences of the study will be shared through the article.

When the data will become available and for how long

Data access will begin 6 months after the results are printed.

To whom data/document is available

Researchers working in academic and scientific institutions and those working in industry.

Under which criteria data/document could be used

In order to further study on the treatment of Urinary Incontinence according to our study protocol

From where data/document is obtainable

Leila Ghanbaryan: lghanbaryan@yahoo.com

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

Written request via email one month after the publication of the article

Comments