

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 61 5283 2978

Email address

l-ghanbaryan@razi.tums.ac.ir

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 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

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

City

Tehran

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 before 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

Street address

Farhangian Clinic, Moallem Square, Moallem Street

City

Behbahan

Province

Khuzestan

Postal code
6361914561
Phone
+98 61 5273 4260
Email
Lghanbaryan@yahoo.com

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
Leila Ghanbaryan
Street address
Imam Khomeini Hospital, Gharib Street, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1616
Email
Lghanbaryan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
sixth floor, Central Organization of Tehran University, corner of Qods Street, Keshavarz Boulevard, Deputy of Research and Technology, Tehran
City
Tehran
Province
Tehran
Postal code
1417653911
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
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
Tehran University of Medical Sciences
Full name of responsible person
Leila Ghanbaryan
Position
PhD candidate of Traditional Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
No. 27, Sarparast Ave., Taleghni St.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8897 4535
Email
lghanbaryan@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Malihe Tabarraie Arani
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
School of Traditional Medicine, Tehran University of Medical Sciences, Giti Alley, Vafamanesh Street, Heravi Square, Pasdaran Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1668753961
Phone

+98 21 2298 8565

Email

dr.mtabarraie@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Leila Ghanbaryan

Position

PHD candidate of Traditional Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No. 27, Sarparast Ave., Taleghni St.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8897 4535

Fax

+98 21 8899 1829

Email

Lghanbaryan@yahoo.com

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