

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

effectiveness of radiofrequency treatment on mixed urinary incontinence and vulvovaginal atrophy

Protocol summary

Study aim

effectiveness of radiofrequency treatment on symptoms of Iranian menopausal women with mixed urinary incontinence and vulvovaginal atrophy

Design

Two arm parallel group randomised trial

Settings and conduct

This study will be done with the participation of women referred to pelvic floor clinic of Valiasr Hospital in Tehran.

Participants/Inclusion and exclusion criteria

vulvovaginal atrophy (VVA) at least one year past from the termination of menstruation presence of VVA symptoms

Intervention groups

Intervention group 2: In RF therapy group, all patients have 3 sessions of treatment, with 4-6 weeks frequency. Each session will be held in groups for 30 minutes with a working temperature range of 40-45°C

Main outcome variables

Urinary incontinence includes the frequency of urinary leakage, urine leakage, the effect of urine leakage on quality of life and urinary leakage time.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190708044143N2**

Registration date: **2020-02-10, 1398/11/21**

Registration timing: **prospective**

Last update: **2020-02-10, 1398/11/21**

Update count: **0**

Registration date

2020-02-10, 1398/11/21

Registrant information

Name

Farima Mohamadi

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effectiveness of radiofrequency treatment on mixed urinary incontinence and vulvovaginal atrophy

Public title

effectiveness of radiofrequency on mixed urinary incontinence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

history of UI symptoms having sexual intercourse having sexual problems due to vulvovaginal atrophy vulvovaginal atrophy symptoms sexual dysfunction

Exclusion criteria:

urinary infection hematuria pelvic organ prolapse pregnancy ICS>2 delivery in less than a year abnormal

vaginal bleeding damaged vaginal tissue

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

According to random numbers table

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

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No.78, Moosivand avenue, Shariati street

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Province

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1933983911

Approval date

2019-05-01, 1398/02/11

Ethics committee reference number

IR.TUMS.IKHC.REC.1398.035

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

Mixed Urinary Incontinence

ICD-10 code

N39.4

ICD-10 code description

Other specified urinary incontinence

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

Urinary incontinence includes the frequency of urinary leakage, urine leakage, the effect of urine leakage on quality of life and urinary leakage time.

Timepoint

Before intervention, second and third sessions after intervention

Method of measurement

ICIQ-SF questionnaire

Secondary outcomes**1****Description**

Vaginal atrophy including burning, itching, dryness, dispersion and dysuria

Timepoint

Before intervention, second and third sessions after intervention

Method of measurement

Visual analog score

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

Intervention group: In RF therapy group, all patients have 3 sessions of treatment, with 4-6 weeks frequency. Each session will be held in groups for 30 minutes with a working temperature range of 40-45°C.

Category

Treatment - Other

2**Description**

Control group: no treatment

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinic of pelvic floor of Valiasr Hospital in Tehran

Full name of responsible person

Fatemeh Dolatshad

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vic-Chancellor in Research of 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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Person responsible for updating data

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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

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

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