

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of the impact of radiofrequency in improving symptoms in women with the pelvic floor muscle spasm

Protocol summary

Study aim

Assessment of the impact of radiofrequency in improving symptoms in women with the pelvic floor muscle spasm

Design

This is a pre-and post-interventional study performed on 22 women with painful spasms of the pelvic floor muscle.

Settings and conduct

In this interventional study, 22 women with painful spasms of the pelvic floor muscle in Yas and Imam Khomeini hospitals are selected by convenience sampling.

Participants/Inclusion and exclusion criteria

Inclusion criteria included women aged 18 to 40 years with painful spasm of the pelvic floor muscle. Exclusion criteria: women with metal implants such as intrauterine device (IUD), women with active infection, vaginal unhealed tears, smokers, patients with pelvic floor anatomical disorders and withdraw to participate.

Intervention groups

For all participants, radiofrequency is performed using the Dynamic Quadripolar Radiofrequency device. This device continuously produces variable and dynamic electromagnetic waves in its four electrodes, allowing the relevant diathermic effect to concentrate and penetrate the posterior pelvic tissues without requiring invasive needles. The four-ring electrodes of this device work between 1.0 and 1.3 MHz and their maximum output power are 55 watts. For all participants, at least one treatment session is done. Then according to the patient's compliance and urogynecology fellowship opinion, the total number of treatment sessions required for each patient is determined. The treatment session is planned every two weeks.

Main outcome variables

Pain and pelvic floor dysfunction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220620055225N2**

Registration date: **2022-07-15, 1401/04/24**

Registration timing: **prospective**

Last update: **2022-07-15, 1401/04/24**

Update count: **0**

Registration date

2022-07-15, 1401/04/24

Registrant information

Name

Khadijeh Adabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 8217

Email address

kh_adabi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the impact of radiofrequency in improving symptoms in women with the pelvic floor muscle spasm

Public title
The impact of radiofrequency on the pelvic floor muscle spasm

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Aged 18 to 40 years Women with painful spasm of the pelvic floor muscle
Exclusion criteria:
Women with metal implants such as intrauterine device (IUD) Women with active infection Vaginal unhealed tears Smoker Patients with pelvic floor anatomical disorders Withdrawal to participate

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences
Street address
Research Ethics Committees of Imam Khomeini Hospital Complex, Dr. Gharib Street, Keshavarz Boulevard.
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2022-05-10, 1401/02/20
Ethics committee reference number

IR.TUMS.IKHC.REC.1401.034

Health conditions studied

1

Description of health condition studied

Painful spasm of the pelvic floor muscle

ICD-10 code

G89.4

ICD-10 code description

Chronic pain syndrome

Primary outcomes

1

Description

Pain

Timepoint

Twice, at the initiation and at the end of the study

Method of measurement

Visual analog scale

2

Description

The pelvic floor dysfunction

Timepoint

Twice, at the initiation and at the end of the study

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For all participants, radiofrequency is performed using the Dynamic Quadripolar Radiofrequency device. This device continuously produces variable and dynamic electromagnetic waves in its four electrodes, allowing the relevant diathermic effect to concentrate and penetrate the posterior pelvic tissues without requiring invasive needles. The four-ring electrodes of this device work between 1.0 and 1.3 MHz and their maximum output power are 55 watts. For all participants, at least one treatment session is done. Then according to the patient's compliance and urogynecology fellowship opinion, the total number of treatment sessions required for each patient is determined. The treatment session is planned every two weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Khadijeh Adabi

Street address

Yas hospital, Next to the Sarv St., North Nejatollahi Str., Karim khan Ave.

City

Tehran

Province

Tehran

Postal code

1597856511

Phone

+98 21 8608 9089

Email

kh_adabi@sina.tums.ac.ir

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Khadijeh Adabi

Street address

Imam Khomeini Hospital Complex, Dr. Gharib Street, Keshavarz Boulevard.

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1416634793

Phone

+98 21 6381 9836

Email

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

Khadijeh Adabi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Yas hospital, Next to the Sarv St., North Nejatollahi Str., Karim khan Ave.

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Tehran

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Postal code

1598718311

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Fax**Email**

kh_adabi@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The anonymous study data is potentially shareable.

When the data will become available and for how long

After the manuscript is published.

To whom data/document is available

No limitations.

Under which criteria data/document could be used

The data is only available to the project manager, Dr. Khadijeh Adabi, and any analysis must be done with her opinion.

From where data/document is obtainable

Dr. Khadijeh Adabi

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

Any request must be sent by e-mail with its proposal to Dr. Khadijeh Adabi.

Comments