

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation of the effect of radiofrequency in the repair of pelvic floor disorders in postpartum women

Protocol summary

Study aim

Evaluation of the effect of radiofrequency in the repair of pelvic floor disorders in postpartum women

Design

This is a pre-and post-interventional study performed on 50 postpartum women.

Settings and conduct

In this interventional study, 50 postpartum women in Yas and Imam Khomeini hospitals are selected by convenience sampling.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age 18 to 40 years, postpartum women (with at least 6 weeks after their vaginal delivery), by diagnosing pelvic floor dysfunction based on the women's history and clinical examination. Criteria for not entering: women with metal implants such as intrauterine device (IUD), women with active infection, vaginal unhealed tears, smoker and withdrawal to participate.

Intervention groups

For all participants, radiofrequency therapy is performed using a Votiva bipolar RF device implanted in the vagina. The Urogynecology Fellowship determines the number of treatment sessions. Also, pelvic floor muscle tone at rest and at maximal pelvic muscle contractions is measured by a musculoskeletal simulator 3 times (before the first and second sessions of RF treatment and two weeks after) for each patient regardless of the number of RF sessions.

Main outcome variables

Rest pelvic floor muscle tone and maximal pelvic muscle contractions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220620055225N1**

Registration date: **2022-06-22, 1401/04/01**

Registration timing: **prospective**

Last update: **2022-06-22, 1401/04/01**

Update count: **0**

Registration date

2022-06-22, 1401/04/01

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

2022-07-23, 1401/05/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of radiofrequency in the repair of pelvic floor disorders in postpartum women

Public title

The effect of radiofrequency in the repair of pelvic floor disorders in postpartum women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 18 to 40 years Postpartum women (with at least 6 weeks after their vaginal delivery) By diagnosing pelvic floor dysfunction based on the women's history and clinical examination

Exclusion criteria:

Women with metal implants such as intrauterine device (IUD) Women with active infection Vaginal unhealed tears Smoker 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: **50**

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

2022-02-27, 1400/12/08

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.476

Health conditions studied

1

Description of health condition studied

Postpartum care

ICD-10 code

Z39

ICD-10 code description

Encounter for maternal postpartum care and examination

Primary outcomes

1

Description

Rest pelvic floor muscle tone

Timepoint

3 times, before the first and second sessions of RF treatment and two weeks after

Method of measurement

Musculoskeletal simulator

2

Description

Maximal pelvic muscle contractions

Timepoint

3 times, before the first and second sessions of RF treatment and two weeks after

Method of measurement

Musculoskeletal simulator

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For all participants, radiofrequency therapy is performed using a Votiva bipolar RF device implanted in the vagina. The Urogynecology Fellowship determines the number of treatment sessions. Also, pelvic floor muscle tone at rest and at maximal pelvic muscle contractions is measured by a musculoskeletal simulator 3 times (before the first and second sessions of RF treatment and two weeks after) for each patient regardless of the number of RF sessions.

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 street , North
Nejatollahi street , 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.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2047

Email

kh_adabi@sina.tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Vice-Dean of Research of Tehran University of Medical
Sciences, Dr. 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

Karim Khan Blvd., North Nejat Elahi St., Yas Hospital

City

Tehran

Province

Tehran

Postal code

1598718311

Phone

+98 21 8894 8217

Fax**Email**

kh_adabi@sina.tums.ac.ir

Person responsible for scientific 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

Karim Khan Blvd., North Nejat Elahi St., Yas Hospital

City

Tehran
Province
Tehran
Postal code
1598718311
Phone
+98 21 8894 8217
Fax
Email
kh_adabi@sina.tums.ac.ir

kh_adabi@sina.tums.ac.ir

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

All data is potentially shareable after unidentified participants.

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

Person responsible for updating data

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

Karim Khan Blvd., North Nejat Elahi St., Yas Hospital

City

Tehran

Province

Tehran

Postal code

1598718311

Phone

+98 21 8894 8217

Fax

Email