Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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)

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+98 21 8894 8217

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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
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1597856511
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kh_adabi@sina.tums.ac.ir

2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
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Street address
Imam Khomeini Hospital Complex, Dr. Gharib Street, Keshavarz Boulevard.
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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
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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
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1598718311
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Position
Associate professor
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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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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

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