Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

A clinical trial to compare the effectiveness of the vaginal radiofrequency with placebo in preventing the prolapse of pelvic organs after surgery

Protocol summary

Study aim
To compare the effectiveness of the vaginal radiofrequency with placebo in preventing the prolapse of pelvic organs after surgery

Design
In this randomized and double-blind clinical trial, 60 patients will be randomly selected using blocks and randomized into parallel and control groups.

Settings and conduct
Patients candidate for prolapse surgery referring to Imam Khomeini Hospital, Tehran, Iran are chosen as the participants of the study. In this double-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive the vaginal radiofrequency and control will receive placebo treatment. The patients and person responsible for data collection are blind to group allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with pelvic organ prolapse. Exclusion criteria: Patients with active or recurrent genital infection (genital herpes, candidiasis); recurrent urinary tract infection; history of pelvic radiotherapy or vaginal brachytherapy; history of reconstructive pelvic surgery.

Intervention groups
The intervention group will receive vaginal radiofrequency 6 weeks after prolapse surgery. The control group will receive vaginal radiofrequency vaginal radiofrequency without energy and on an off status 6 weeks after prolapse surgery.

Main outcome variables
degree of pelvic organ prolapse, quality of life and sexual satisfaction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220906055897N1**
Registration date: **2022-10-08, 1401/07/16**
Registration timing: **prospective**

Last update: **2022-10-08, 1401/07/16**
Update count: **0**

Registration date
2022-10-08, 1401/07/16

Registrant information

Name
Parivash Jelodarian

Name of organization / entity

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Iran (Islamic Republic of)

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+98 916 602 9855

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-10-23, 1402/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical trial to compare the effectiveness of the vaginal radiofrequency with placebo in preventing the prolapse of pelvic organs after surgery

Public title

The effectiveness of vaginal radiofrequency in preventing the prolapse of pelvic organs after surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with pelvic organ prolapse

Exclusion criteria:

Patients with active or recurrent genital infection (genital herpes, candidiasis) Recurrent urinary tract infection History of pelvic radiotherapy or vaginal brachytherapy History of reconstructive pelvic surgery

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the restricted randomization method of block randomization base on statistical analysis system (SAS), computer software. All blocks are the same size, and in this two-group experiment we will have 6 blocks (including 3 participants in the intervention group and 3 participants in the control group). Random allocation software software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and data analyzer do not know which groups are located. The samples in the intervention and control group did not know whether they received the the vaginal radiofrequency or placebo (without energy and on an off status) treatment. The statistician will receive questionnaires as anonymously and in form A and B, and he does not know which are intervention and control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Imam Khomeini Hospital, Tehran University of Medical Sciences

Street address

Dr. Gharib Street, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-08-30, 1401/06/08

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.127

Health conditions studied

1

Description of health condition studied

Pelvic organ prolapse

ICD-10 code

N81

ICD-10 code description

Female genital prolapse

Primary outcomes

1

Description

The degree of pelvic organ prolapse

Timepoint

Before, 6, 10, 14 and 18 weeks after surgery

Method of measurement

The pelvic organ prolapse quantifications system (POP-Q)

2

Description

Quality of life

Timepoint

Before, 6, 10, 14 and 18 weeks after surgery

Method of measurement

Pelvic floor distress inventory (PFDI-20)

Secondary outcomes

1

Description
Sexual satisfaction
Timepoint
Before, 6, 10, 14 and 18 weeks after surgery
Method of measurement
The female sexual function index (FSFI)

Intervention groups

1

Description
Intervention group: The intervention group will receive vaginal radiofrequency 6 weeks after prolapse surgery, then three sessions with a one-month interval. Radiofrequency is equipped with an energy-harvesting integrated circuit, with 64 microneedles vaginal pen, 200 microns in diameter and 1 mm in length. The duration of each session will be 15 to 20 minutes.
Category
Treatment - Devices

2

Description
Control group: The control group will receive vaginal radiofrequency vaginal radiofrequency without energy and on an off status 6 weeks after prolapse surgery, then three sessions with a one-month interval. Radiofrequency is equipped with an energy-harvesting integrated circuit, with 64 microneedles vaginal pen, 200 microns in diameter and 1 mm in length. The duration of each session will be 15 to 20 minutes.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Parivash Jelodarian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mehdi Fakoorsaghieh
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Vice Chancellor for Research, Tehran University of Medical Sciences, Enqelab Street
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1417614411
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research@ut.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
Parivash Jelodarian
Position
Fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
In our study non of the personal data of patients will be shared. Only data that are related to outcomes of intervention will be shared.
When the data will become available and for how long
6 months after publishing the results
To whom data/document is available
The research data is exclusively accessible to the researchers working at universities and centers for scientific research.
Under which criteria data/document could be used
The research data is exclusively accessible to the researchers working at universities and centers for scientific research.
From where data/document is obtainable
Parivash Jelodarian provides the data analysis to the applicants via email: parivash1359@gmail.com
What processes are involved for a request to access data/document
Applicants can send emails to him and receive a response within a week.
Comments