

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

Country

Iran (Islamic Republic of)

Phone

+98 916 602 9855

Email address

parivash1359@gmail.com

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		Placebo	Used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria		Other design features	
Inclusion criteria:	Patients with pelvic organ prolapse	Secondary Ids	empty
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	Ethics committees	
Age	No age limit	1	
Gender	Female	Ethics committee	
Phase	2-3	Name of ethics committee	Ethical committee of Imam Khomeini Hospital, Tehran University of Medical Sciences
Groups that have been masked	- Participant - Outcome assessor	Street address	Dr. Gharib Street, Keshavarz Blvd
Sample size	Target sample size: 60	City	Tehran
Randomization (investigator's opinion)	Randomized	Province	Tehran
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.	Postal code	1419733141
Blinding (investigator's opinion)	Double blinded	Approval date	2022-08-30, 1401/06/08
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.	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

Street address

Imam Khomeini Hospital, Dr. Gharib Street, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 0000

Email

parivash1359@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehdi Fakoorsaghieh

Street address

Vice Chancellor for Research, Tehran University of Medical Sciences, Enqelab Street

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6640 0059

Fax

Email

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

Street address

Imam Khomeini Hospital, Dr. Gharib Street, Keshavarz Blvd

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Tehran

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Person responsible for scientific 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
Street address
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Person responsible for updating data

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
Street address
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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 none 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