

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effects of adding radiofrequency to conventional pelvic physiotherapy in postpartum urinary incontinence, compared to conventional pelvic physiotherapy alone, on clinical symptoms and MRI findings, a Randomized Clinical Trail

Protocol summary

Study aim

Investigating the effects of adding radiofrequency to conventional pelvic physiotherapy in postpartum urinary incontinence, compared to conventional pelvic physiotherapy alone, on clinical symptoms and MRI findings

Design

Single-blind, randomized, parallel-group clinical trial with 75 participants allocated in a 1:1:1 ratio using permuted block randomization.

Settings and conduct

The study will be conducted at Al-Zahra and Vali-e-Asr Hospitals, Tabriz, Iran. Eligible participants will be randomly assigned to one of three groups. Outcome assessors and the statistical analyst will be blinded to group allocation, and participants and treating therapists will be instructed not to disclose treatment allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primiparous women aged 18–45 years with postpartum urinary incontinence. Exclusion criteria: Pelvic floor disorders before pregnancy, subsequent pregnancy, cesarean delivery without an active second stage of labor, and previous pelvic surgery.

Intervention groups

Participants will be randomly assigned to one of three groups: Group1: radiofrequency plus conventional pelvic floor physiotherapy (pelvic floor muscle training, electrical stimulation, and biofeedback when indicated); Group2: radiofrequency therapy alone; Group3: routine postpartum care.

Main outcome variables

PRAFAB questionnaire score; pelvic floor muscle strength; pelvic floor muscle endurance; pelvic floor muscle resting tone; quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140811018760N13**

Registration date: **2026-07-08, 1405/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2026-07-08, 1405/04/17**

Update count: **0**

Registration date

2026-07-08, 1405/04/17

Registrant information

Name

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2027-06-22, 1406/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of adding radiofrequency to conventional pelvic physiotherapy in postpartum urinary incontinence, compared to conventional pelvic physiotherapy alone, on clinical symptoms and MRI findings, a Randomized Clinical Trial

Public title

Effect of TECAR therapy on postpartum urinary incontinence

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Primiparous women aged 18–45 years who are between 6 weeks and 12 months postpartum following a vaginal delivery. A PRAFAB questionnaire score of ≥ 8 . Presence of at least one of the following structural or functional abnormalities on the baseline clinical assessment or magnetic resonance imaging (MRI): * Levator hiatus area $> 25 \text{ cm}^2$ during the Valsalva maneuver; * Levator ani muscle avulsion; * Reduced relative thickness of the puborectalis muscle compared with the contralateral side Ability to perform a voluntary pelvic floor muscle contraction. Willingness and ability to participate in a 6–8-week treatment program and undergo two MRI assessments. Provision of written informed consent.

Exclusion criteria:

Subsequent pregnancy during the study period. Cesarean delivery without an active second stage of labor (because of the different pathophysiology of levator ani muscle injury). Severe pelvic organ prolapse (POP-Q stage ≥ 2) or the need for specialized conservative or surgical treatment. Active vaginal infection, untreated bacterial vaginosis, or pelvic inflammatory disease. History of pelvic floor disorders before pregnancy, including urinary incontinence, fecal incontinence, pelvic organ prolapse, or chronic pelvic pain. Neuromuscular disorders affecting pelvic floor muscle contraction (e.g., multiple sclerosis, spinal cord injury, or severe peripheral neuropathy). Presence of active electronic or metallic implants (e.g., an intrauterine device [IUD], cardiac pacemaker, or neurostimulator) that may interfere with radiofrequency treatment Pelvic or perineal surgery within the previous 6 months. Receipt of specialized pelvic floor treatment (e.g., supervised pelvic floor muscle training, radiofrequency therapy, or laser therapy) within the previous 3 months. Intolerance to the vaginal radiofrequency probe. Claustrophobia preventing MRI assessment. Presence of active myofascial trigger points in the pelvic floor muscles on physical examination.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation sequence will be generated by an independent statistician using a computer-generated randomization sequence based on permuted blocks of varying sizes (2, 4, and 6), with a 1:1:1 allocation ratio across the three study groups. Allocation concealment will be ensured by placing the group assignments in sequentially numbered, opaque, sealed envelopes prepared by an independent individual not involved in participant recruitment or assessment. The envelopes will remain sealed until a participant has been enrolled. Following enrollment, the next envelope in the sequence will be opened, and the participant will be assigned to the indicated study group.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will employ a single-blind design in which the outcome assessors and the statistical analyst will remain blinded to participants' group allocation. Because of the nature of the interventions, blinding of participants and treating therapists is not feasible. To preserve assessor blinding, participants and treating therapists will be instructed not to disclose or discuss treatment allocation with the outcome assessors at any time during the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

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Rehabilitation Faculty, Tabriz University of Medical Sciences, Daneshgah Ave

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Approval date

2026-06-07, 1405/03/17

Ethics committee reference number

IR.TBZMED.REC.1405.152

Health conditions studied**1****Description of health condition studied**

Postpartum urinary incontinence

ICD-10 code

N39.4

ICD-10 code description

Other specified urinary incontinence

Primary outcomes**1****Description**

urinary incontinence

Timepoint

The measurement will be performed in three stages: before the start of treatment, immediately after the end of treatment, and tree month after the last treatment session.

Method of measurement

PRAFAB Questionnaire

Secondary outcomes**1****Description**

Pelvic floor dysfunction during pregnancy and postpartum

Timepoint

The measurement will be performed in three stages: before the start of treatment, immediately after the end of treatment, and tree month after the last treatment session.

Method of measurement

PFQ-postpartum and pregnancy Questionnaire

Intervention groups**1****Description**

Intervention group1: (Conventional Pelvic Floor Physiotherapy):Participants in this group will receive conventional pelvic floor physiotherapy, including education regarding pelvic floor anatomy and function, pelvic floor muscle training (PFMT), biofeedback for participants who are unable to correctly identify or contract their pelvic floor muscles, and intravaginal electrical stimulation when indicated. The supervised treatment program will be conducted for 6 weeks, with two sessions per week, each lasting 45-60 minutes. To maintain treatment effects, participants will subsequently perform a home-based PFMT program for an additional 6 weeks, with a frequency of 3-4 sessions

per week.

Category

Rehabilitation

2**Description**

Intervention group 2: (Radiofrequency Therapy):Participants in this group will receive radiofrequency therapy using capacitive-resistive diathermy (TECAR therapy).Phase 1: Intravaginal Capacitive RadiofrequencyAn intravaginal electrode covered with a disposable sheath and appropriate lubricant will be inserted into the vagina and applied for 8-10 minutes using either a static position or very gentle movements. Energy delivery will be uniform and performed without mechanical pressure. Treatment intensity will be adjusted within the subthermal to mild thermal range according to patient feedback, producing a comfortable, pain-free sensation of warmth.Phase 2: External Resistive RadiofrequencyExternal resistive radiofrequency will be applied using a resistive surface electrode over the external perineal region for 10-12 minutes. The electrode will be moved slowly and uniformly in circular motions over the treatment area without excessive mechanical pressure. Treatment intensity will be maintained within the subthermal to mild thermal range and adjusted according to patient tolerance.Participants will receive a total of 12 treatment sessions, delivered twice weekly for 6 consecutive weeks.

Category

Rehabilitation

3**Description**

Control group(Routin care): Participants in the control group will receive routine postpartum care as provided in the participating healthcare centers and will not receive any active pelvic floor physiotherapy intervention during the study period. Specifically, they will not receive pelvic floor education, pelvic floor muscle training, electrical stimulation, biofeedback, manual therapy, or radiofrequency treatment.Routine care will consist of standard medical follow-up, general non-structured advice, and other non-physiotherapy interventions that are routinely provided as part of usual postpartum clinical care.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra hospital

Full name of responsible person

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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<https://rehabilitation.tbzmed.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Fariba Ghaderi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
"There is no further information"
Study Protocol

Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document

1. The data file of the participants will be designed and collected without mentioning the name and with ID definition. 2. The study protocol will be published in the form of an article after the start of data collection. 3. The statistical analysis map will be prepared in SPSS file format after data collection. 4. The informed consent form of this study was designed and will be available to the participants. 5. The clinical study report will be prepared and published in the form of six-month reports and the final report.

When the data will become available and for how long

Access to data begins six months after publication of study results

To whom data/document is available

The study protocol and final study results will be available to the public after publication. Access to other data is done upon request. Under which criteria data/document could be used

Under which criteria data/document could be used

In order to design other research projects in this field, data will be sent. From where data/document is obtainable

From where data/document is obtainable

To receive the data and documents of this study, the scientific officer of this project can be contacted via e-mail. email address: What processes are involved for a request to access data/document

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

After sending and reviewing the request for access to the data, in accordance with the principle of confidentiality of the personal information of the study participants, the data will be sent within a few days to a few weeks.

Comments