Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Fariba Ghaderi
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1333 4647
Email address
ghaderif@tbzmed.ac.ir

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 Trail

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 cm² 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

Street address
Rehabilitation Faculty, Tabriz University of Medical Sciences, Daneshgah Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5166414766

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 Questionaire

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 Questionaire

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
Fariba Ghaderi
Street address

ALzahra Hospital,South Artesh Ave., Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5167631444

Phone
+98 41 3334 5121

Fax
+98 41 3334 5121

Email
ghaderif@tbzmed.ac.ir

Web page address

2

Recruitment center

Name of recruitment center
Vali-asr Hospital

Full name of responsible person
Fariba Ghaderi

Street address
Vali-asr Hospital, The beginning of Zafaranieh,Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
14469337140

Phone
+98 41 3332 1736

Email
ghaderif@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Khosro Adibkia

Street address
Faculty of Rehabilitation Sciences, University of Medical Sciences, 29 Bahman Blvd, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166414766

Phone
+98 41 3337 2072

Email
rehab.fac@tbzedmed.ac.ir

Web page address
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

Street address
Rehabilitation faculty., Tabriz university of medical sciences., Golgasht street., Azadi street

City
Tabriz

Province
East Azarbaijan

Postal code
5166414766

Phone
+98 41 3335 2072

Email
ghaderif@tbzmed.ac.ir

Person responsible for scientific 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

Street address
Rehabilitation faculty., Tabriz university of medical sciences., Golgasht street., Azadi street

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Phone

+98 41 3335 2072

Email

ghaderif@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Fariba Ghaderi

Position

Professor- PhD of physiotherapy

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation faculty, Tabriz University of Medical Sciences.

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Phone

+98 413339771

Fax

Email

ghaderif@tbzmed.ac.ir

Web page address

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