Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effectiveness of pelvic floor biofeedback combined with autologous platelet-rich plasma injection in comparison to biofeedback as a monotherapy in rehabilitation of women with stress urinary incontinence.

Protocol summary

Study aim
Evaluating the effectiveness of biofeedback treatment of pelvic floor muscles and platelet rich plasma injection compared to biofeedback treatment as a mono-therapy treatment in the rehabilitation of women with stress urinary incontinence.

Design
A parallel-group, single-blind, randomized controlled clinical trial.

Settings and conduct
Patients with stress urinary incontinence who are referred to physical medicine and rehabilitation clinic of Shiraz University of Medical Sciences for non-surgical treatment and rehabilitation.

Participants/Inclusion and exclusion criteria
Women with clinical symptoms of urinary stress incontinence; Age more than 20 and less than 70 years; Patients who wish to have non-surgical procedures.Exclusion criteria: Patients with prolapse (stage>II); Cervical malignancy and dysplasia; acute/recurrent urinary tract infection; pelvic reconstruction surgery; pregnancy; abnormal uterine bleeding; taking anti-platelet and anticoagulant drugs; Psychiatric diseases; history of surgery due to urinary incontinence; uncontrolled diabetes; neurogenic urinary incontinence; Urge incontinence

Intervention groups
Intervention group: 24 patients, both of which will receive pelvic floor muscle rehabilitation treatments in 35-minute sessions, once a week, including 20 minutes of electrical stimulation with a vaginal probe and15 minutes of pelvic biofeedback which will be performed for the patient in for one month. Then, 3 shots of platelet-rich plasma will be performed at 4-week intervals in the anterior 1/3 of the vagina.The control group: 24 patients who will only undergo pelvic floor muscle rehabilitation biofeedback for an average of 4 weekly sessions (once a week). In both groups patients are instructed to perform daily Kegel exercises.

Main outcome variables
Urinary stress incontinence; Platelet-rich plasma infusion; Pelvic floor biofeedback; sexual performance; Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221106056413N1**
Registration date: **2023-01-24, 1401/11/04**
Registration timing: **prospective**

Last update: **2023-01-24, 1401/11/04**
Update count: **0**

Registration date
2023-01-24, 1401/11/04

Registrant information

Name
Tayebeh Sadat Salehi Rihani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-21, 1402/01/01
Expected recruitment end date
2024-03-20, 1403/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effectiveness of pelvic floor biofeedback combined with autologous platelet-rich plasma injection in comparison to biofeedback as a monotherapy in rehabilitation of women with stress urinary incontinence.

Public title
Effectiveness of platelet-rich plasma injection in treatment of stress urinary incontinence.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women with clinical symptoms of urinary incontinence. Age 35-55 patients opting for non-surgical management.
Exclusion criteria:
Stage>II prolapse Cervical dysplasia and malignancy Recurrent urinary tract infection Pelvic reconstruction surgery Pregnancy Abnormal uterine bleeding Anti-platelet drug medication Psychological disorders History of surgery due to urinary incontinence Uncontrolled diabetes Neurogenic urinary incontinence Urge urinary incontinence
Age
From **20 years** old to **70 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible candidates to enter the study were assigned by random allocation using block randomization method. 48 recruited individuals were randomly assigned to one of the two groups of (intervention pelvic biofeedback and platelet rich plasma injection) and a control group (pelvic biofeedback), which will use block randomization with different block sizes. The size of the blocks will be a multiple of 2 and a divisor of 48 (2, 4, and 6). Initially, the block sizes are chosen randomly. Then for each block, different permutations are randomly determined by the Randomization Allocation Software. In each block, the number of people in the groups is equal, and blinding is used to not reveal the permutations in the last people of each block.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, patients will not know about how they are grouped and the details of the interventions performed.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Physical & Rehabilitation Medicine department, Faghihi hospital, Zand Street
City
Shiraz
Province
Fars
Postal code
7134846114
Approval date
2022-01-30, 1400/11/10
Ethics committee reference number
IR.SUMS.MED.REC.1400.584

Health conditions studied

1

Description of health condition studied
Stress urinary incontinence
ICD-10 code
N39.3
ICD-10 code description
Stress incontinence (female) (male)

Primary outcomes

1

Description
Stress urinary incontinence
Timepoint
The effectiveness of platelet-rich plasma injection and pelvic floor biofeedback after 4 weekly sessions of biofeedback and 3 monthly sessions of PRP shots on women suffering from stress urinary incontinence.
Method of measurement
International Consultation on Incontinence Questionnaire- Female Lower Urinary Tract Symptom

(ICIQ-FLUTS) long form and short form

Secondary outcomes

1

Description
Sexual Function
Timepoint
The effectiveness of platelet-rich plasma injection and pelvic floor biofeedback after 4 weekly sessions of biofeedback and 3 monthly sessions of PRP shots on sexual function of women suffering from stress urinary incontinence.
Method of measurement
Female Sexual Function Index Pelvic incontinence Sexual Questionnaire-12

2

Description
Quality of life
Timepoint
The effectiveness of platelet-rich plasma injection and pelvic floor biofeedback after 4 weekly sessions of biofeedback and 3 monthly sessions of PRP shots on quality of life of women suffering from stress urinary incontinence.
Method of measurement
International Consultation on Incontinence Questionnaire- Quality of Life (ICIQ-QOL)

Intervention groups

1

Description
Intervention group: 24 patients undergoing pelvic floor muscle rehabilitation treatment as 35-minute sessions, once a week, including 20 minutes of electrical stimulation with a vaginal probe with biphasic alternating current settings with a frequency of 5 Hz and a pulse width of 300 microseconds and current intensity from 1 to 100 The milliampere is adjusted to the level tolerated by the patient. Then 15 minutes of biofeedback with pelvic floor rehabilitation protocol will be performed for the patient in 4 weekly sessions (one session per week) for one month. In between sessions, the patient should perform Kegel exercises 6 times a day. In this group, after 4 sessions of pelvic rehabilitation, one shot of platelet-rich plasma in the anterior 1/3 wall of the vagina is performed. Three shots of platelet-rich plasma are performed at 4-week intervals. Before performing the procedure, a full blood test will be performed for the patients for platelet count, prothrombin time and check liver enzymes to rule out liver diseases, and a complete urine test. Then the injection process will be explained to the patients and patients with the following abnormalities will be excluded from the trial: 1- Platelet disorders 2- Thrombocytopenia 3- Hypofibrinogenemia 4- Patients who are not hemodynamically stable 5- Acute/chronic infection 6- Chronic liver disease 7- Patients who use anticoagulants 8- Malignancy. Eligible patients will be referred to the pain and rehabilitation clinic, and after obtaining informed consent from the patients, two 10 ml samples of blood will be taken, and after centrifugation, two 5 ml samples of platelet-rich plasma will be prepared for administration. Gel-based Royagen kits will be used to prepare platelet-rich plasma. The procedure is done with the patient placed in the lithotomy position, the desired area will be numbed with local anesthesia, and the injection process will be performed under sterile conditions. The prepared plasma will be injected using a 27G needle in the anterior 1/3 of the vaginal wall around the middle urethra, which is located about 1 cm behind the urethra, with a depth of 1.5 cm (2 ml of the solution in Behind the urethra and 1.5 ml on both sides of the urethra at 11, 12 and 1 clocks). This procedure will be repeated every 4 weeks for 3 months.
Category
Treatment - Other

2

Description
Control group: 24 patients will undergo pelvic floor muscle rehabilitation treatment as 35-minute sessions, once a week, including 20 minutes of electrical stimulation with a vaginal probe with biphasic alternating current settings with a frequency of 5 Hz and a pulse width of 300 microseconds and current intensity from 1 to 100 The milliampere is adjusted to the level tolerated by the patient. Then 15 minutes of biofeedback with pelvic floor rehabilitation protocol will be performed for the patient in 4 weekly sessions (one session per week) for one month. In between sessions, the patient should perform Kegel exercises 6 times a day.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Clinic of Shiraz Medical University
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Phone
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Email
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
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Full name of responsible person
Tayebeh Sadat Salehi Rihani
Position
Resident
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available