# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 71 3231 9040

**Email address**

tayebe.sadat.s.r@gmail.com


**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**
Sharareh Roshanzamir
**Street address**
Namazi Square
**City**
Shiraz
**Province**
Fars
**Postal code**
۷۱۳۴۸۱۴۷۳۴
**Phone**
+98 71 3212 7001
**Fax**
+98 71 3647 4673
**Email**
motahari@sums.ac.ir

**Web page address**

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Mahtab Memarpour
**Street address**
Shiraz University of Medical Sciences Central Building, Zand Street
**City**
Shiraz
**Province**
Fars
**Postal code**
7134814336
**Phone**
+98 71 3230 5410
**Email**
info@sums.ac.ir
**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**
Shiraz University of Medical Sciences
**Full name of responsible person**
Tayebeh Sadat Salehi Rihani
**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Physical Medicine
**Street address**
No. 2, East 14th Ave., Sabari Blvd., Tehran
**City**
Tehran
**Province**
Fars
**Postal code**
1956819173
**Phone**
+98 21 2645 2587
**Email**
tayebe.sadat.s.r@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Tayebeh Sadat Salehi Rihani
**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Physical Medicine
**Street address**
No. 2, East 14th Ave., Sabari Blvd., Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1956819173
**Phone**
+98 21 2645 2587
**Email**
tayebe.sadat.s.r@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Tayebeh Sadat Salehi Rihani
**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Physical Medicine
**Street address**
No. 2, East 14th Ave., Sabari Blvd., Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1956819173
**Phone**
+98 21 2645 2587
**Email**
tayebe.sadat.s.r@gmail.com

## 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