

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 and 15 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

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Province

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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

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+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