

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study on the effect of paraurethral injection of platelet rich plasma on the treatment of stress urinary incontinence in women

Protocol summary

Study aim

Determination of the effect of paraurethral injection of platelet rich plasma on the treatment of stress urinary incontinence in women who coming to kerman besat clinic in 2017

Design

Pilot Randomized control trial with 2 parallel groups .not blinded

Settings and conduct

Patients referring to Besat Clinic of Kerman are divided to the intervention and control groups, according to the random numbers table after having the inclusion criteria . A total of 20 patients were studied. 10 patients were selected as control and 10 patients were randomly selected for experimental groups. In the urology unit of Shahid Bahonar Hospital of Kerman University of Medical Sciences, according to the criteria of the study, patients in the control group received standard treatment Mid Urethral Sling and in the intervention group, patients are candidates for paraurethral PRP injections.

Participants/Inclusion and exclusion criteria

The study population consisted of patients aged 30-65 years with stress urinary incontinence (SUI) who referred to the Kerman Bessat Clinic in 1396, which did not respond to conservative, medication and pelvic floor exercises, and according to the inclusion criteria they candidate for paraurethral Platelet rich plasma (PRP) injection

Intervention groups

10 patients in the intervention group were candidates for paraurethral injection of PRP and 10 patient in the control group received standard treatment of SUI (midurethral sling surgery).

Main outcome variables

State of Severity of stress urinary incontinence State of quality of life in stress urinary incontinence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171201037697N1**

Registration date: **2019-01-04, 1397/10/14**

Registration timing: **retrospective**

Last update: **2019-01-04, 1397/10/14**

Update count: **0**

Registration date

2019-01-04, 1397/10/14

Registrant information

Name

atefe eslami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4452 0136

Email address

atefe_eslami70@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-03-19, 1396/12/28

Actual recruitment start date

2017-04-04, 1396/01/15

Actual recruitment end date

2017-08-22, 1396/05/31

Trial completion date

2017-10-17, 1396/07/25

Scientific title

Study on the effect of paraurethral injection of platelet rich plasma on the treatment of stress urinary incontinence in women

Public title

Study on the effect of PRP on the treatment of urinary incontinence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female Existence of Stress urinary incontinence(SUI) symptom Confirm of SUI based on urodynamic test Positive cough stress test Age 30 - 65 Yr No reply to conservative treatment or interested in surgical treatment for SUI

Exclusion criteria:

post void residual (PVR) more than 100cc evidence of Detrusor overactivity in urodynamic test before surgery Positive history for midurethral sling surgery or any surgery on external genitalia ,bladder, bladder neck or urethra Genitourinary system infection Genitourinary system malignancy Positive history of bleeding disorders or recent anticoagulant treatment Positive recent history of Genitourinary fistula or urethral diverticulum Positive recent history of cytocele or rectocele Uncontrolled diabetes mellitus Any contraindication for surgery

Age

From **30 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on random number table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kerman university of medical

sciences

Street address

Kerman.haft bagh alavi AVE.paradis of kerman university of medical sciences

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2017-09-25, 1396/07/03

Ethics committee reference number

IR.KMU.REC.1396.1270

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

The Severity of urinary incontinence

Timepoint

0,1,3 month after intervention

Method of measurement

International Consultation on Incontinence Questionnaire(ICIQ) , The Questionnaire for Urinary Incontinence Diagnosis(QUID) , clinical examination(cough stress test)

2

Description

Quality of Life

Timepoint

0,1,3 month after intervention

Method of measurement

The Incontinence Quality of Life questionnaire(I-QOL)

Secondary outcomes

empty

Intervention groups

1

Description

intervention group:blood sampling was done.20ml of intravenous blood was taken on anticoagulant (ACD) and centrifuged in15ml Falcon tubes for 10 minutes at 800 RPM, and after separation and transfer of platelet-rich

plasma"Which was deposited on RBCs", was added to 15ml new falcons and re-centrifuged for 15 minutes at 3500 RPM, after removing of upper part of plasma , concentrated platelet was obtained. About 3ml of this concentrate was taken with an insulin syringe and then in the operating room under general anesthesia with cyctourethroscopy and special needles injected at two points of the rabdosphingter(in the middle of the urethra) by the urologist. and then Platelet-rich-plasma was injected at two points with lower depth in the submucosa separately for supportive effect .This method did not require hospitalization after intervention.

Category

Treatment - Surgery

2

Description

Control group: after receiving satisfaction and performing routine preoperative tests, in the operating room and under general anesthesia, patients were treated with midurethral sling surgery by the urologist (standard treatment of urinary stress incontinence). they were admitted and monitored for 24-24 hours after surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat clinic of kerman

Full name of responsible person

Dr.azar daneshpajoo

Street address

Besat clinic of kerman.,jahad blvd

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5700

Email

Azdaneshpajoo@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr.abbas pardakhti

Street address

pardis of kerman university of medical sciences ,
Haft bagh alavi blvd

City

Kerman

Province

Kerman

Postal code

:13555-76169

Phone

+98 34 3226 3855

Email

abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Atefe eslami

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

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Eghlid .shhrmian village.mahdieh clinic

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7381689611

Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr.azar daneshpajoo

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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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

No more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period from 1398

To whom data/document is available

Accessible for researcher in academic institutions

Under which criteria data/document could be used

Email and obtain permission from the original researcher (Dr. Azar Daneshahi Pajoo)

From where data/document is obtainable

Dr.azar daneshpajoo

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

After sending the email to the researcher of the project, applicants will be given a maximum of 1 month

Comments

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Atefe eslami

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

Street address

mahdieh clinic . Shahrman village

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Postal code

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