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 surgury).

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 incontinenece
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Female Existence of Stress urinary incontinence(SUI) symptom Confirm of SUI based on urodinamic test Positive cough stress test Age 30 - 65 Yr No reply to conversative treeatment or intrested 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 cyctocele 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 ofter 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 ofter 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 surgury 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 daneshpajooh

Street address

Besat clinic of kerman.,jahad blvd

City

Kerman

Province

Kerman

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7616913555

Phone

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Email

Azdaneshpajooh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr.abbas pardakhti

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

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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

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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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position
assisstant professor

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Person responsible for updating data

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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 Pajooh)

From where data/document is obtainable
Dr.azar daneshpajooh

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