Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of platelet-rich plasma (PRP) injection in Kelly plication in women with stress urinary incontinence

Protocol summary

Study aim
Determining the effect of platelet rich plasma (PRP) injection in Kelly plication in women with stress urinary incontinence

Design
Randomized, Controlled, Single-blinding clinical trial, with the parallel groups, Phase 3 on 60 patients

Settings and conduct
In this study, 60 women with stress urinary incontinence referring to Khurshid Hospital, Isfahan will be randomly included and divided into two groups. In one group, only the Kelly plication surgery method, and in the second group, in addition to the usual surgery method, PRP will be prescribed after the surgery. Due to the single-blind of this study, the researcher knows the type of intervention group. Still, the patient, the person who examines the patient's condition, and the person analyzing the data will not know the type of groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria are women over 20 years old, moderate to mild stress urinary incontinence, diagnosis of stress urinary incontinence based on history and physical examination and questionnaire, failure to respond to medical treatments for stress urinary incontinence, and written informed consent to participate in the present study. Exclusion criteria include the presence of detrusor hyperactivity in urodynamics, history of stress urinary incontinence surgery, urinary tract infection, and Obesity.

Intervention groups
Control group: will be treated by Kelly plication surgery method. Intervention group: After Kelly plication surgery, PRP will also be performed.

Main outcome variables
Pain, the amount of urine leakage; Frequency of urinary leakage

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221208056749N1**
Registration date: **2023-05-23, 1402/03/02**
Registration timing: **prospective**

Last update: **2023-05-23, 1402/03/02**
Update count: **0**

Registration date
2023-05-23, 1402/03/02

Registrant information

Name
Maryam Hajihashemi

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-05, 1402/03/15

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

Investigating the effect of platelet-rich plasma (PRP) injection in Kelly plication in women with stress urinary incontinence

Public title
Investigating the effect of platelet rich plasma (PRP) injection in women with stress urinary incontinence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women over 20 years Moderate to mild stress urinary incontinence Diagnosing stress urinary incontinence based on history, physical examination and questionnaire Failure to respond to medical treatments for stress urinary incontinence Written informed consent to participate in the present study
Exclusion criteria:
Existence of detrusor hyperactivity in urodynamics History of stress urinary incontinence surgery Urinary tract infection Obesity (BMI greater than 30)
Age
From **20 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The method is permuted block randomization. In this way, first using online software (sealedenvelope), a sequence of random numbers will be created and by the same software, the generated numbers will be divided into 6 blocks of 10. Which is an equal number in each block will be 5 items from the intervention group and 5 items from the control group. So by doing each block, 5 patients (equally) will be assigned to each group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Considering that patients do not know how to perform the Kelley pillification method and are unconscious during the intervention. Therefore, one of the groups was only treated with this method and for the second group, in addition to this method, PRP injection will be used.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences
Street address
Isfahan, Azadi Square, Isfahan University of Medical Sciences
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Province
Isfehan
Postal code
8184853542
Approval date
2022-09-06, 1401/06/15
Ethics committee reference number
IR.MUI.MED.REC.1401.218

Health conditions studied

1

Description of health condition studied
Stress urinary incontinence
ICD-10 code
N39.49
ICD-10 code description
Other specified urinary incontinence

Primary outcomes

1

Description
Pain
Timepoint
One month, 3 months, 6 months and 12 months after surgery
Method of measurement
Visual Analogue Scale

2

Description
Amount of urine leakage
Timepoint
One month, 3 months, 6 months and 12 months after surgery
Method of measurement
Urinary distress inventory (UDI-6)

3

Description
Frequency of urinary leakage
Timepoint
One month, 3 months, 6 months and 12 months after surgery

Method of measurement
Incontinence Questionnaire–Urinary Incontinence Short Form (ICIQ-UI SF)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before surgery, blood samples of patients are taken and sent to the laboratory to prepare PRP. To prepare PRP, a volume of 12 cc was taken from peripheral blood of the patient, mixed with sodium citrate, centrifuged for 10 minutes at 1200 rpm, and the obtained plasma is rich in platelets. After the Kelley pillication surgery and in the operating room, immediately before the injection, 0.5 cc of calcium chloride solution is mixed to degranulate the platelets and injected in the proximal areas of the duct at 3, 6, and 9 o'clock
Category
Treatment - Surgery

2

Description
Control group: Patients of this group will be treated by the Kelley pillification method
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr. Maryam Haj Hashemi
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2

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Sponsors / Funding sources

1

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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Maryam Haj Hashemi
Position
Associate Professor, Pelvic Floor Disorders Fellowship, faculty
Latest degree
Specialist
Other areas of specialty/work
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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available