

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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 Hajhashemi

Name of organization / entity

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Iran (Islamic Republic of)

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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 (sealed envelope), 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
City
Esfahan
Province
Isfahan
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

Street address

Felezi bridge, Shahid Beheshti Hospital

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Esfahan

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2**Recruitment center****Name of recruitment center**

Al-Zahra Hospital

Full name of responsible person

Dr. Maryam Haj Hashemi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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

Gynecology and Obstetrics

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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