

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of simultaneous injection of autologous fat with platelet-rich plasma on the fat thickness of the bladder neck and proximal urethra in women with stress urinary incontinence: a before after clinical trial

Protocol summary

Summary

Objectives: To assess the effect of simultaneous injection of autologous fat with PRP on the fat thickness of the bladder neck and proximal urethra. Design: a before and after clinical trial. Setting and conduct: Eligible women with stress urinary incontinence who will refer to the Shahid Beheshti Hospital during the study period will be enrolled in to the trial. Inclusion criteria: (a) having stress urinary incontinence; (b) female sex; (c) age of 20 to 80 years. Exclusion criteria: (a) presence of moderate to severe cystocele; (b) detrusor overactivity in urodynamic test; (c) history of ureteral surgery; (d) hypermobility of the ureter (more than 30 degrees); (e) obesity (BMI more than 30) Intervention: injection of 1 ml subcutaneous fat at the proximal of urethra at 3, 6, and 9 o'clock positions seven times plus injection of 0.5 ml platelet-rich plasma at the proximal of urethra at 3, 6, and 9 o'clock positions seven times. Control: comparison with the patients' condition before intervention. Primary outcome: Assessing the fat thickness of the bladder neck and proximal urethra in mm using MRI before intervention and one week and 3 months later. Secondary outcome: Assessing the urethra bleeding one week after intervention with question form the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409299014N41**
Registration date: **2014-10-07, 1393/07/15**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-07, 1393/07/15

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of simultaneous injection of autologous fat with platelet-rich plasma on the fat thickness of the bladder neck and proximal urethra in women with stress urinary incontinence: a before after clinical trial

Public title

Effect of simultaneous injection of autologous fat with platelet-rich plasma on the fat thickness of the bladder neck and proximal urethra in women with stress urinary

incontinence

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: (a) having stress urinary incontinence; (b) female sex; (c) age of 20 to 80 years. Exclusion criteria: (a) presence of moderate to severe cystocele; (b) detrusor overactivity in urodynamic test; (c) history of ureteral surgery; (d) hypermobility of the ureter (more than 30 degrees); (e) obesity (BMI more than 30)

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **23**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2014-03-02, 1392/12/11

Ethics committee reference number

D/P/16/35/9/4200

Health conditions studied

1

Description of health condition studied

stress urinary incontinence

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence

Primary outcomes

1

Description

Assessing the fat thickness of the bladder neck and proximal urethra in mm

Timepoint

before intervention and one week and 3 months later

Method of measurement

using MRI

Secondary outcomes

1

Description

Assessing the urethra bleeding

Timepoint

one week after intervention

Method of measurement

with question form the patients

Intervention groups

1

Description

injection of 1 ml subcutaneous fat at the proximal of urethra at 3, 6, and 9 o'clock positions seven times plus injection of 0.5 ml platelet-rich plasma at the proximal of urethra at 3, 6, and 9 o'clock positions seven times

Category

Treatment - Drugs

2

Description

comparison with the patients' condition before intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr Adel Eslami

Street address

Shahid Beheshti Hospital, Eram Ave
City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti Hospital

Full name of responsible person

Dr Adel Eslami

Position

Resident of Urology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti Hospital

Full name of responsible person

Dr Mohammad Ali Amirzargar

Position

Urologist

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty