

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effect of transurethral plasma rich platelet combined with autologous fat injection versus autologous fat injection on abdominal leak point pressure in patient with stress urinary incontinence: a double blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of transurethral plasma rich platelet combined with autologous fat injection versus autologous fat injection on abdominal leak point pressure in patient with stress urinary incontinence. **Design:** a double blinded randomized clinical trial. **Setting and conduct:** All eligible patients 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) patients with stress urinary incontinence; (b) abdominal leak point pressure less than 100 cm of water. **Exclusion criteria:** (a) hyperactivity of the detrusor muscle; (b) contraindication of anesthesia; (c) presence of anatomical disorder in bladder; (d) platelet disorder. **Intervention:** Transurethral injection of 25 ml plasma rich platelet combined with 25 ml autologous fat single dose. **Control:** Transurethral injection of 25 ml autologous fat single dose. **Primary outcome:** evaluation of improvement of urinary incontinence before intervention and every 3 months after intervention for 18 months by history taking. **Secondary outcome:** (a) evaluation of urinary retention one week after intervention by history taking; (b) thromboembolism 48 hours after intervention by physical examination; (c) urinary infection one week after intervention by history taking.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410219014N44**
Registration date: **2014-10-27, 1393/08/05**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-27, 1393/08/05

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of transurethral plasma rich platelet combined with autologous fat injection versus autologous fat injection on abdominal leak point pressure in patient with

stress urinary incontinence: a double blinded randomized clinical trial

Public title

Effect of transurethral plasma rich platelet combined with autologous fat injection versus autologous fat injection on abdominal leak point pressure in patient with stress urinary incontinence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) patients with stress urinary incontinence; (b) abdominal leak point pressure less than 100 cm of water. Exclusion criteria: (a) hyperactivity of the detrusor muscle; (b) contraindication of anesthesia; (c) presence of anatomical disorder in bladder; (d) platelet disorder.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 46

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: 46 envelopes will be prepared including 23 envelopes having plasma rich platelet combined with autologous fat and 23 envelope having autologous fat. Then, each envelope will be given randomly to every patient. Blinding: Neither the patients nor the physician who will exam the patients will aware of the type of intervention. Therefore, the study will be run as double blinded.

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 Hamadan

City

Hamadan

Postal code

6517838695

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

P/16/35/9/2886

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

evaluation of improvement of urinary incontinence

Timepoint

before intervention and every 3 months after intervention for 18 months

Method of measurement

by history taking

Secondary outcomes

1

Description

evaluation of urinary retention

Timepoint

one week after intervention

Method of measurement

by history taking

2

Description

thromboembolism

Timepoint

48 hours after intervention

Method of measurement

by physical examination

3

Description

urinary infection

Timepoint

one week after intervention

Method of measurement

by history taking

Intervention groups

1

Description

Transurethral injection of 25 ml plasma rich platelet combined with 25 ml autologous fat single dose.

Category

Treatment - Drugs

2

Description

Transurethral injection of 25 ml autologous fat single dose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr Masood Jafari

Street address

Shahid Beheshti Hospital, Eram Bul.

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

City

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 Masood Jafari

Position

Resident of Urology

Other areas of specialty/work

Street address

Shahid Beheshti Hospital, Eram Bul.

City

Hamadan

Postal code

Phone

+98 81 3838 0717

Fax

Email

m.jafari2442 @gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti Hospital

Full name of responsible person

Dr Ali Amirzargar

Position

Urologist

Other areas of specialty/work

Street address

Shahid Beheshti Hospital, Eram Bul.

City

Hamadan

Postal code

Phone

+98 81 3838 0717

Fax

Email

dr-amirzargar@yahoo.com

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