

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of autologous muscle derived stem cells and fibroblasts injection into the women's paraurethral tissues for the treatment of stress urinary incontinence.

Protocol summary

Study aim

Study the effect of autologous muscle derived stem cells and fibroblasts injection into the women's paraurethral tissues for the treatment of stress urinary incontinence

Design

Clinical trial without control group, community based, not blinded, non-randomized study

Settings and conduct

This study is conducted in the field of urology. Its location is Bahonar Hospital and the Comprehensive Center for Stem Cells and Reconstructive Medicine of Kerman University of Medical Sciences. After the patient is selected by the physician, the stem cells are injected into the bladder sphincter in one session. Results are checked 1,3, 6 and 12 months after injection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged between 40 to 65 years old; Stress Urinary Incontinence symptoms; Urodynamic stress incontinence confirmed by multichannel urodynamic testing; Positive cough stress test; desire to surgical correction of stress urinary incontinence; inadequate response to conservative treatment of SUI. Exclusion criteria: History of surgery on external genitalia, bladder neck, bladder or urethra; Desire to future childbearing; History of bleeding or current anti-coagulation therapy; Current genitourinary fistula or urethral diverticulum

Intervention groups

In this study there will be one group in which stem cells are injected into patients once and followed up after 1,3,6 and 12 months after injection.

Main outcome variables

Closure pressure, Urinary flow rate, Maximum detrusor pressure during voiding, Amount of urine left, severity of urinary symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140911019125N7**

Registration date: **2020-05-02, 1399/02/13**

Registration timing: **retrospective**

Last update: **2020-05-02, 1399/02/13**

Update count: **0**

Registration date

2020-05-02, 1399/02/13

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 32 24618

Email address

afarsinejad@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of autologous muscle derived stem cells and fibroblasts injection into the women's paraurethral tissues for the treatment of stress urinary incontinence.

Public title

Treatment of stress urinary incontinence in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged between 40 to 65 years old Stress Urinary Incontinence symptoms Urodynamic stress incontinence confirmed by multichannel urodynamic testing Positive cough stress test Patients desire to surgical correction of stress urinary incontinence inadequate response to conservative treatment of SUI

Exclusion criteria:

History of surgery on external genitalia, bladder neck, bladder or urethra Desire to future childbearing History of bleeding or current anti-coagulation therapy Current genitourinary fistula or urethral diverticulum Active urinary infection Uncontrolled Diabetes

Age

From **40 years** old to **65 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **25**

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

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Haft Bagh blvd

City

Kerman

Province

Kerman

Postal code

7616911333

Approval date

2017-01-22, 1395/11/03

Ethics committee reference number

IR.KMU.REC.1395.349

Health conditions studied

1

Description of health condition studied

Stress Urinary Incontinences in women

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence (female) (male)

Primary outcomes

1

Description

Closure pressure

Timepoint

Before intervention and 1,3,6,12 months after intervention

Method of measurement

Urodynamic test

2

Description

Urinary flow rate

Timepoint

Before intervention and 1,3,6 and 12 months after intervention

Method of measurement

Urodynamic test

3

Description

Maximum detrusor pressure during voiding

Timepoint

Before intervention and 1,3,6,12 months after intervention

Method of measurement

Urodynamic test

4

Description

Amount of urine left

Timepoint

Before intervention and 1,3,6,12 months after intervention

Method of measurement

Urodynamic test

5

Description

Severity of urinary symptoms

Timepoint

Before intervention and 1,3,6,12 months after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The sample taken from the patient is brought to the laboratory. The sample is then digested enzymatically and cultured. After the cells reach a sufficient confluency, 40 million cells are injected into the bladder sphincter.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahonar Hospital

Full name of responsible person

Azar Danesh Pajooch

Street address

Bahonar Hospital; Gharani street

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

azdaneshpajooch@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Kerman University of Medical Sciences, Haft Bagh blvd

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Kerman

Postal code

7616911333

Phone

+98 34 3226 3855

Email

abpardakhty@kmu.ac.ir

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

Kerman University of Medical Sciences

Full name of responsible person

Alireza Farsinejad

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Hematology

Street address

Paramedical college, Kerman University of Medical Sciences, Haft Bagh blvd

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Province

Kerman

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7616911333

Phone

+98 34 3132 5374

Email

afarsinejad@kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Alireza Farsinejad

Position

Associate professor

Latest degree

Ph.D.

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 additional data.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

In our study non of the personal data of patients will be shared. Only data that are related to outcomes of intervention will be shared.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

The data will be available for people working in academic institutions and clinicians.

Under which criteria data/document could be used

Applicants are only allowed to use received data in clinical and they are not allowed to published them

From where data/document is obtainable

1- Phone: 034-31325374 2- e-mail: afarsinejad@kmu.ac.ir 3- Fax: 034-31325375 4- address: Dr. Alireza Farsinejad; Kerman University of Medical science; Haft Bagh blvd

What processes are involved for a request to access data/document

Applicant can receive information after contact and send e-mail up to 10 days.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Alireza Farsinejad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Hematology

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