

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Clinical trial of comparison of medium-term results of single incision mini-sling and stem cell therapy in the treatment of women's stress urinary incontinence

Protocol summary

Study aim

Comparison of medium-term results of single incision mini-sling and stem cell therapy in the treatment of women's stress urinary incontinence

Design

Interventional clinical trial, single blinded, parallel groups, randomised

Settings and conduct

30 patients referred to the urology clinic of Kerman University of Medical Sciences were randomly selected and randomly divided into two groups under mini-sling surgery and stem cell injection. The study is double blind, the patient and the outcome assessor are unaware of the type of treatment performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women at the age of 18 years old and over; history of SUI; Failure to respond to conservative managements after 3 months; Urine leak in the initial examination during coughing or Valsalva maneuver ; Non-inclusion criteria: persistent urinary tract infection (UTI); proved VUR; History of previous SUI surgery; history of Bulking agent injection in urethra; history of neurological diseases such as MS, CVA, or muscular dystrophy; Obesity (BMI > 40); Localized fibrosis and stiffness at the injection site in the cystoscopy.

Intervention groups

Intervention group 1 "Surgery group": 15 patients underwent mini-sling surgery Intervention Group 2 "Injection Group": 15 patients were first performed mucosal sampling and then stem cell preparation and underwent stem cell injection.

Main outcome variables

Stress urinary incontinence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190517043609N2**
Registration date: **2020-05-03, 1399/02/14**
Registration timing: **retrospective**

Last update: **2020-05-03, 1399/02/14**

Update count: **0**

Registration date

2020-05-03, 1399/02/14

Registrant information

Name

mohammadali bagherinasabsarab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3222 1600

Email address

ma_bagherinasab_md@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-10-10, 1395/07/19

Expected recruitment end date

2018-10-10, 1397/07/18

Actual recruitment start date

2016-10-10, 1395/07/19

Actual recruitment end date

2018-03-10, 1396/12/19

Trial completion date

2018-06-01, 1397/03/11

Scientific title

Clinical trial of comparison of medium-term results of

single incision mini-sling and stem cell therapy in the treatment of women's stress urinary incontinence

Public title

Comparison of surgery and stem cell therapy in the treatment of women's urinary incontinence

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women at least 18 years old history of SUI (Stress Urinary Incontinence) Failure to respond to conservative managements after 3 months Urine leak in the initial examination during coughing or Valsalva maneuver

Exclusion criteria:

persistent urinary tract infection (UTI) proved Vesicouretral Reflux (VUR) History of previous Stress urinary incontinence surgery history of neurological diseases such as Cerebro Vascular Accident(CVA) ,muscular dystrophy or Multiple Sclerosis(MS) Obesity (Body Mass Index(BMI)> 40) Localized fibrosis and stiffness at the injection site in the cystoscopy high grade cystocele and rectocele (equal to or more than 3 according to the pelvic organ prolapse quantification system (POP-Q) Overactive bladder symptoms (Uninhibited contractions, low capacity, low compliance in urodynamic study) Medium to severe bladder trabeculation and or open bladder neck in cystourethroscopy Residue of urine > 100cc and or maximum flow rates of lower than 15 ml/s Pregnant or intending future pregnancies coagulation disorders history of Bulking agent injection in urethra

Age

From **18 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method is used by using blocks of size 6, in each block consisting 3 part is for surgical intervention group and 3 is for injection intervention group, with the aim that the groups progress in a balanced way over time and This method continues until the sample size reaches 30 people (including 15 intervention groups and 15 control groups or 5 blocks of 6)

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is single blind and the patient do not know the type of treatment (surgery or injection) performed but the primary researcher (physician and data collector) knows the type of treatment

Placebo

Not used

Assignment

Parallel

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; Emam Khomeini blvd

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2016-08-25, 1395/06/04

Ethics committee reference number

IR.KMU.REC.1395.343

Health conditions studied**1****Description of health condition studied**

Stress Urinary incontinence

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence (female) (male)

Primary outcomes**1****Description**

Examination of stress urinary

Timepoint

1, 3, 6 and 12 months after the intervention (surgery or stem cell injection)

Method of measurement

International Urinary Incontinence Questionnaire(IIQ score)

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: In the stem cell injection group: After obtaining written consent, the mucosal tissue sample is separated from the volunteer patients by the physician and placed in a phosphate buffer solution containing antibiotics and amphotericin and sent immediately to the university stem cell center. The cells collected for injection into the patient are given to the physician as a suspension. After obtaining the required amount of stem cells (6 10 10 64), the sample is sent to the urology operating room as freeze, and after melting with normal saline, it is 0.9% diluted (up to 4 cc) and with a cystoscope in two areas in the sphincter. The external urine is injected (8 injections 0.5 cc). After three months, the injection is given again.

Category

Treatment - Surgery

2

Description

Intervention group2: In the other group, for mini-sling surgery with mesh insertion, after venous sedation and lithotomy position with a 1 cm mid-urethral incision, a short arm mesh of Boston company is inserted.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology Clinic of Bahonar Hospital in Kerman

Full name of responsible person

Mahbobe Mirzaie

Street address

Bahonar hospital.Qareney St,Kerman

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

mirzaeimahboubbeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

Kerman University of Medical Sciences; Emam Khomeini blvd

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5700

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

Mahbobe Mirzaie

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Kerman University of Medical Science,Emam khomeini Blv,Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5700

Email

mirzaeimahboubbeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mahbube Mirzaie

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Kerman University of Medical Science;Emam
Khomeini Blv,Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5700

Email

mirzaeimahboubeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mohammadali Bagherinasab

Position

Urology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Kerman University of Medical Sciences; Emam
Khomeini blvd

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5700

Email

ma_bagherinasab_md@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available