Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 freez, 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
mirzaeimahboubeh@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
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 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