

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation and comparison of the effectiveness of two methods of tension free surgical intervertebral medial autologous sling and synthetic vaginal sling in the correction of stress urinary incontinence

Protocol summary

Study aim

Evaluation and comparison of the effectiveness of two methods of tension free surgical intervertebral medial autologous sling(modified sling) and synthetic vaginal sling in the correction of stress urinary incontinence

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 48 patients. Balanced blocks were used for randomization.

Settings and conduct

Hashminejad and Moheb Mehr hospital. Two blind strains

Participants/Inclusion and exclusion criteria

Existence of urinary stress incontinence in history and icq questionnaire and its confirmation by urodynamic evaluation and cough test

Intervention groups

Patients in 2 groups: sling surgery with artificial mesh (TVT, control group) and sling surgery with autologous rectus fascia modified compared to the classical method (intervention group, in the classical method, a fascia incision with a length and width of approximately 1.5 x 9 cm is used and this autologous tissue is placed in the neck of the bladder. In the modified method of this process, a shorter tissue of about 1.5 x 5 cm is used and placed in the mid-urethral in the group of intervention patients). And the aim is to investigate the effectiveness and success of the treatment in two methods

Main outcome variables

Investigating the effectiveness and success of the sling method with artificial mesh. The expectation is: 1- equal efficacy 2- reduction of financial burden - removal of artificial mesh cost 3- reduction of voiding dysfunction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211123053163N1**

Registration date: **2023-04-29, 1402/02/09**

Registration timing: **retrospective**

Last update: **2023-04-29, 1402/02/09**

Update count: **0**

Registration date

2023-04-29, 1402/02/09

Registrant information

Name

gohar haghpanah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 81161

Email address

haghpanahgohar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

2022-04-28, 1401/02/08

Actual recruitment end date

2023-01-05, 1401/10/15

Trial completion date

2023-01-05, 1401/10/15

Scientific title

Evaluation and comparison of the effectiveness of two methods of tension free surgical intervertebral medial

autologous sling and synthetic vaginal sling in the correction of stress urinary incontinence

Public title

Evaluation and comparison of the effectiveness of two methods of tension free surgical intervertebral medial autologous sling and synthetic vaginal sling in the correction of stress urinary incontinence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

stress urinary incontinence

Exclusion criteria:

Urinary tract infection during surgery Suspicion of urogenital malignancy

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **48**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the samples using the randomization method with balanced blocks, people are divided into two intervention and comparison groups, and using this table, the surgical method of each patient is determined and a special code is considered for each patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this process, after selecting the patients for surgical treatment and choosing the type of operation of the patient by means of balanced blocks (48 patients, 8 envelopes of 6 in fact, the envelopes contain 6 F or T labels, the F labels indicate sling surgery with Fascia and T label indicate TVT sling action). After selecting the patient completely randomly from inside the envelopes, a label is given to the patient as the type of random surgery and this label is also considered as the patient code in addition to showing the type of surgery of the patient. With this method, the patient does not have a role in consciously choosing the type of operation. On the other hand, after collecting the data of each patient, this data is provided to the analyzer with the relevant code, and in fact, the analyzer is not aware of the type of operation of the patient, and all the data is analyzed randomly and coded. .

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees of School of Medicine

Street address

Vali nezahd St

City

Tehran

Province

Tehran

Postal code

1969714713

Approval date

2022-04-24, 1401/02/04

Ethics committee reference number

IR.IUMS.FMD.REC.1401.057

Health conditions studied

1

Description of health condition studied

Urinary stress incontinence

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence (female) (male)

Primary outcomes

1

Description

The level of patient satisfaction in urinary control

Timepoint

3 consecutive months after surgery

Method of measurement

Examination with a cough test and the number of pads used daily

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: People who undergo modified sling

surgery
Category
Treatment - Surgery

2

Description
Intervention group 2: This group includes 24 people and the patient's autologous tissue is used instead of artificial mesh.

Category
Treatment - Surgery

3

Description
Control group 1: This group consisted of 24 people and classical synthetic vaginal sling surgery was performed on these people. Placement of artificial mesh in mid-urethral

Category
Treatment - Surgery

4

Description
Intervention group 3: The desired autologous tissue from the rectus fascia is used with a shorter size than the classic method and the placement of this tissue is in the mid-urethral, which in the classic method, this tissue is placed in the neck of the bladder.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Hashemi nezhad Kidney center
Full name of responsible person
Dr Emami
Street address
Vali nezhad St
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support@hkc.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Iran University of Medical Sciences
Full name of responsible person
Dr Bagheri
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr Emami
Position
Doctor
Latest degree
Subspecialist
Other areas of specialty/work
Urology
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Person responsible for updating data

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Haghpanah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

I have not decided yet

When the data will become available and for how long

I have not decided yet

To whom data/document is available

I have not decided yet

Under which criteria data/document could be used

I have not decided yet

From where data/document is obtainable

I have not decided yet

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

I have not decided yet

Comments