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 iciq 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Contact

Name of organization / entity
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Haghpanah

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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