

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The necessity of urodynamic test in the patient with urine stress incontinency to identify patients and improve their quality of life after TOT (Transobturator) surgery.

Protocol summary

Summary

OBJECTIVE: The necessity of urodynamic test in the patients with urine stress incontinency to identify the patients and improve their quality of life after TOT (Transobturator) surgery. **Study design:** A randomized clinical trial study. **Inclusion criteria:** Women between 21 and 45 years old; stress urinary incontinency for 3 months; desire for surgery; negative urinalysis and urine culture. **Exclusion criteria:** Urinary retention in absence of prolapse; previous pelvic surgery in the last 3 months; previous surgery for urinary incontinency; prolapse(grade 2); urination urgency; uncontrolled diabetes; urinary tract or bladder cancer; Pelvic Surgeries. **INTERVENTION:** 48 women with urinary incontinency divided into two groups: 24 patients were randomly assigned to one of two groups. Patients in the first group will be selected for trans-obturator surgery after Urodynamic test and patients in the second group will be selected based on the questionnaire for trans-obturator surgery. After trans-obturator surgery in both groups, the results of the surgery and quality of life (IQOL questionnaire) is going to be compared after 1 and 6 months after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060618655N3**
Registration date: **2017-04-05, 1396/01/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-05, 1396/01/16

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-06-09, 1395/03/20

Expected recruitment end date

2017-06-10, 1396/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The necessity of urodynamic test in the patient with urine stress incontinency to identify patients and improve their quality of life after TOT (Transobturator) surgery.

Public title

The necessity of urodynamic test in the patient with urine stress incontinency to identify patients and improve their quality of life after TOT (Transobturator) surgery.

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Between 21 -45 years old; having stress urinary incontinence for at least 3 months; urinalysis and urine culture tends to surgery. Exclusion criteria: Urinary retention by the absence of prolapse; a medical condition; previous pelvic surgery in the last 3 months; previous surgery for the treatment of urinary incontinence; grade 2 prolapse; patients with urgency urination; uncontrolled diabetes; urinary tract or bladder cancer treatment; Pelvic Surgery

Age

From **21 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Postal code

Approval date

2016-04-25, 1395/02/06

Ethics committee reference number

IR.SUMS.REC.1395.4.145

Health conditions studied

1

Description of health condition studied

Urinary Stress Incontinancy

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence

Primary outcomes

1

Description

The acquiescent ofTOT

Timepoint

Before TOTthen 1and6month after surgery

Method of measurement

IQOL questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Performing Urodynamic test.

Category

Diagnosis

2

Description

Fill out IQOL questionnaire

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zeinab Hospital

Full name of responsible person

Name Naghizadeh

Street address

Defae Moghadas Square, Hazrat Zeinab Hospital

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Shirsz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

Street address

Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Najme Naghizadeh

Position

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*