

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation study between Tention - Free Vaginal Tape and Transobturator Tape in treatment stress incontinence in women

Protocol summary

Summary

This is a study that evaluate the tension-free vaginal tape (TVT) and obturator tape (TOT) procedures in terms of continence results, outcome and complications after a median follow-up of 6 months were compared. The aim of this study was to evaluate the efficacy of the TOT versus the TVT in women with stress urinary incontinence (SUI). This is a prospective randomized clinical trial study on eighty female patients suffering from SUI that were randomly allocated to two groups; TVT (n=40) and TOT (n=40) group. Preoperative and postoperative assessments included a validated Stress and Urge Incontinence Questionnaire, a 24-h pad test. The clinicopathologic parameters of the patients included age, body mass index, onset of incontinence, previous pelvic surgery, parity, delivery, type of anesthesia, operative time, hospital stay, catheter indwelling, postoperative complications and 1, 3 and 6 months follow up of ICIQ.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112148228N4**
Registration date: **2011-12-26, 1390/10/05**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-26, 1390/10/05

Registrant information

Name

Mohammad Reza Darabi Mahboub

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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ghodsa1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Science

Expected recruitment start date

2009-09-14, 1388/06/23

Expected recruitment end date

2010-11-14, 1389/08/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation study between Tention - Free Vaginal Tape and Transobturator Tape in treatment stress incontinence in women

Public title

Effect of two surgery methods in treatment stress incontinence in women

Purpose

Treatment

Inclusion/Exclusion criteria

Include criteria: Women with incontinence without history of surgery for cytocele with SUI. Exclude criteria: neurogenic bladder urgency incontinence; Metabolic disorder; urinary infection; over activity of detrusor in urodynamic test.

Age

From **50 years** old to **75 years** old

Gender

Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 80

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

Ethical committee of Mashhad University of Medical Science

Street address

Ghoreshi building, Daneshgah Ave

City

Mashhad

Postal code

Approval date

2009-07-23, 1388/05/01

Ethics committee reference number

87608

Health conditions studied

1

Description of health condition studied

Stress Incontinence

ICD-10 code

N39.3

ICD-10 code description

Use additional code (N32.8), if desired, to identify overactive bladder or detrusor muscle hyperactivity.
N39.4 Other specified urinary incontinence Overflow
Reflex Urge incontinence Use additional code (N32.8), if desired, to identify overactive bladder

Primary outcomes

1

Description

Rate of incontinence in 24 hours

Timepoint

Before Intervention

Method of measurement

History of patients

Secondary outcomes

1

Description

Rate of incontinence along a 24hours

Timepoint

Months of 1 , 3 and 6 after Intervention

Method of measurement

History

Intervention groups

1

Description

Trans Obturator tape (TOT) procedure

Category

Treatment - Surgery

2

Description

Tension free vaginal tape (TVT) procedure

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Science

Full name of responsible person

Dr Zhila Sheikhi

Street address

Department of urology , Mashhad University of Medical Science

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Science

Full name of responsible person

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Department of urology , Imam Reza hospital

City

Mashhad

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Mashhad University of Medical Science
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

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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