Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the incidence of urinary incontinence in two methods of transobturator and mini sling surgery and urodynamic markers in patients with urinary incontinence

Protocol summary

Study aim

Comparison of the incidence of urinary incontinence in two methods of transobturator and mini sling surgery and urodynamic markers in patients with urinary incontinence

Design

randomized clinical trial Randomization with computerized program for random allocation and sealed envelopes:at the time of open envelope surgery and the type of operation was determined. To estimate the sample size, studies will be used from similar studies that similar groups have been compared. Considering the results of the comparison in the change of hospital stay and the duration of surgery in a similar study, this study was conducted using the comparative formulas of the meanings considering alpha = 0.5 and beta = 0.2 and the probability of the loss of study samples in each A group of 35 people is considered. .

Settings and conduct

In this RCT study in Shahid Hasheminejad Hospital, women who are referred to Urology Clinic with complaints of stress urinary incontinence included in the study.

Participants/Inclusion and exclusion criteria

Women with urinary incontinence were studied EXCLUSION CRITERIA: overactive bladder under medical treatment high post void residue neurological deficit pelvic inflammatory disease pelvic organ prolapse recurrence of prior surgery

Intervention groups

women with stress urinary incontinence They were divided into mini-sling and transobturator groups The transobturator group was designated as a control according to a further history of usage

Main outcome variables

urodynamic study FSFI questionnaire(female sexual function index) ICIQ questionnaire(International Consultation on Incontinence Questionnaire) pain questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180407039216N1**
Registration date: **2018-04-22, 1397/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-22, 1397/02/02**
Update count: **0**

Registration date

2018-04-22, 1397/02/02

Registrant information

Name

Abdolreza Momtazan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4489 3413

Email address

momtazan.ar@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

2018-04-21, 1397/02/01

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date

empty

Scientific title

Comparison of the incidence of urinary incontinence in two methods of transobturator and mini sling surgery and urodynamic markers in patients with urinary incontinence

Public title

anti incontinence surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

stress urinary incontinence female

Exclusion criteria:

non stress urinary incontinence POP high PVR neurological deficit PID recurrence of prior surgery under medical treatment

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

random allocation Individuals were randomly assigned to a TOT or mini sling technique using a random sequence in a 1: 1 ratio design and were randomly assigned to a series of sealed envelopes.

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 Iran University of Medical Science

Street address

Valinezhad Ave., Valie Asr Ave.,

City

Tehran

Province

Tehran

Postal code

1969714713

Approval date

2018-03-04, 1396/12/13

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9311254002

Health conditions studied

1

Description of health condition studied

female urinary incontinence

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence (female) (male)

Primary outcomes

1

Description

Changes in urodynamic quantities

Timepoint

before and after surgery

Method of measurement

urodynamic study , female sexual function questionaire (FSFI questionaire) ,International Consultation on Incontinence Questionnaire(ICIQ questionaire)

Secondary outcomes

1

Description

Change in sexual activity score

Timepoint

before and 8 week after surgery

Method of measurement

FSFI questionaire(female sexual function index)

Intervention groups

1

Description

Intervention group: mini sling anti incontinence surgery

Category

Treatment - Surgery

2

Description

Control group: transobturator anti incontinence surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Hasheminezhad Kidney center

Full name of responsible person
Abdolreza Momtazan

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Valinezhad Ave., Valie Asr Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Seyed Kazem Malakouti

Street address
Hemmat highway,next to milad tower ,Iran University of medicine

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1449614535

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

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
Abdolreza Momtazan

Position
urology rezident

Latest degree
Medical doctor

Other areas of specialty/work
Urology

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Person responsible for updating data

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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