

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison between result of trans-obturator tape method and anterior vaginal colporrhaphy in treatment of stress urinary incontinency

Protocol summary

Summary

The objectives of this study is the comparison between result of trans-obturator tape method and anterior vaginal colporrhaphy in treatment of stress urinary incontinency. We will assay 60 women with stress incontinence and maximum cystocele grade 2 (POP-Q) referred to Gynecology clinic of Kerman Afzalipoor Hospital. The patients randomly will be divided in two groups : anterior colporrhaphy and Transobturator Tap surgery). Exclusion criteria: : Other Urinary system Disorders; Chronic Disease ; Use Medicines contribute to stress urinary incontinency; Alchole or Drug users. Patient Visited 1,6, and 12 month after surgery to diagnose complications and results of treatment (Jacobs and Blavias classification: cure: no incontinence, improvement : less than once in two weeks, failure: more than once in week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204109433N1**

Registration date: **2012-04-18, 1391/01/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-18, 1391/01/30

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Kerman University Of Medical Sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2012-04-19, 1391/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between result of trans-obturator tape method and anterior vaginal colporrhaphy in treatment of stress urinary incontinency

Public title

Comparison between trans-obturator tape method and anterior vaginal colporrhaphy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Stress Urinary Incontinency; Cystocel with maximum grade 2 (POP-Q) Exclusion criteria: : Other Urinary system Disorders; Chronic Disease (for example: psychiatry diseases, DM, Heart Failure, Chronic Lung Disease, Neurologic Disorders(like MS , CVA),; Use Medicins like: benzodiazepines, Anticholinergic, Prazocine, Ca Channel Blockers; Alchole or Drug users.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

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**

Kerman University Of Medical Sciences/ Research
Deputy

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Ebne Sina Street, Jahad Boulevard

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Approval date

2010-07-06, 1389/04/15

Ethics committee reference number

k/89/154

Health conditions studied**1****Description of health condition studied**

stress urinary incontinence

ICD-10 code

N39.3

ICD-10 code description

Stress incontinence

Primary outcomes**1****Description**

stress urinary incontinency

Timepoint

1,6,12 month

Method of measurement

quastion

Secondary outcomes**1****Description**

complications: urethral erosion, bladder perforation,
urethral or vaginal perforation,abccess, hematoma in
opration site, new urinary disorders

Timepoint

intraopration, 1, 6 nad 12 month aftre surgery

Method of measurement

physical examination

Intervention groups**1****Description**

Transe Obturator Tape

Category

Treatment - Surgery

2**Description**

Anterior Colporrhaphy surgery

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Afzalipoor Hospital

Full name of responsible person

Samira Sohbati

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Department Of Obstetrics And Gynecology, Afzalipoor
Hospital, Kerman University Of Medical Sciences

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

Dr Zohreh Salari

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Hospital, Kerman University Of Medical Sciences

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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

Kerman 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

Department Of Obstetrics And Gynecology, Afzalipoor Hospital, Kerman University Of Medical Sciences

Full name of responsible person

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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