

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of performing and not performing the prophylactic surgery for urinary incontinence in advanced pelvic organ prolapse

Protocol summary

Summary

(1) Main outcome: Comparison of performing and not performing the prophylactic surgery for urinary incontinence in advanced pelvic organ (2) Design: Accidental (3) Setting and conduct: 60 patients with advanced pelvic organ prolapse without a history of urinary incontinence, enrolled into the study. (Patients with advanced pelvic organ prolapse who suffer from urinary incontinence are excluded from the study.) Randomly 30 patients undergo urinary incontinence surgery in addition to prolapse surgery (TOT+ Standard surgery) and 30 patients undergo prolapse surgery without urinary incontinence surgery (Standard surgery). Examination findings and ICIQ-SF questionnaire are recorded for all patients before surgery and 1 and 2 months after surgery. Patients will be followed up by phone or invitation to clinic for 2 months and asked if SUI is occurred. (4) Participants including major eligibility criteria: Sample size is 60 patients. Inclusion criteria are women with advanced pelvic prolapse without urinary incontinence symptoms. Exclusion criteria are women with advanced vaginal prolapse with urinary incontinence symptoms. (5) Intervention: Women with advanced pelvic organ prolapse without urinary incontinence undergo prophylactic surgery for urinary incontinence (TOT). Intervention is done concurrent with the standard surgery for advanced pelvic prolapse. (6) Main outcome measures (variables): Development of SUI after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013041513025N1**

Registration date: **2013-06-15, 1392/03/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-15, 1392/03/25

Registrant information

Name

Neda Shoari

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 6950

Email address

nedashoari@irimc.org

Recruitment status

Recruitment complete

Funding source

Women's reproductive health research center, Tabriz university of medical sciences.

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of performing and not performing the prophylactic surgery for urinary incontinence in advanced pelvic organ prolapse

Public title

Comparison of performing and not performing the prophylactic surgery for urinary incontinence in

advanced pelvic organ prolapse

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Women with advanced vaginal prolapse without urinary incontinence symptoms.
Exclusion criteria: Women with advanced vaginal prolapse with urinary incontinence symptoms; Women who are not candidate for surgery due to comorbidities.(cardiac, pulmonary, etc)

Age
No age limit

Gender
Female

Phase
2-3

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
Ethics Committee of Tabriz University of Medical Science

Street address
Research vice-chancellor, Central building number 2, Tabriz University of Medical Sciences, Golgasht street.

City
Tabriz

Postal code

Approval date
2013-03-13, 1391/12/23

Ethics committee reference number
5/4/12136

Health conditions studied

1

Description of health condition studied
Pelvic organ prolapse

ICD-10 code

N81

ICD-10 code description

Female genital prolapse

Primary outcomes

1

Description

Development of SUI after surgery

Timepoint

Before intervention, 1 month after intervention and 2 months after intervention.

Method of measurement

Standard questionnaire ICIQ-SF

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 patients undergo urinary incontinence surgery in addition to prolapse surgery (Standard surgery+ TOT).

Category

Treatment - Surgery

2

Description

Control group: 30 patients undergo urinary incontinence surgery without prolapse surgery (Standard surgery).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Talegani educational and therapeutic center

Full name of responsible person

Neda Shoari

Street address

Talegani educational and therapeutic center, Rah-Ahan street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz university of

medical sciences

Full name of responsible person

Dr Parvin Bastani

Street address

Daneshgah Ave, Tabriz university of medical sciences

City

Tabriz

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, Tabriz 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

Tabriz university of medical science

Full name of responsible person

Dr Parvin Bastani

Position

Assistant professor, Gynecologist, Orogyneology fellowship

Other areas of specialty/work

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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