Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Evaluation of bladder function in patients with overactive bladder after cystocele repair

Protocol summary

Study aim
Determination of bladder function in women with overactive bladder after cystocele repair
Design
A single arm clinical trial, on 50 patients
Settings and conduct
In this study, 50 patients with the overactive bladder are included in the study. Due to having only one treatment group, there is no blinding. These patients undergo cystocele repair. Before, one and six months after the intervention, bladder function is evaluated and recorded.
Participants/Inclusion and exclusion criteria
Inclusion criteria include age 18 years and older, diagnosis of overactive bladder, frequent urination more than eight times a day, feeling of urinary urgency more than once a day, being married, and satisfaction to participate in the study. Exclusion criteria include breastfeeding, pregnancy, use of contraceptive methods, anticholinergic contraindication, need for a catheter, obstruction of the bladder outlet, and history of genitourinary surgery.
Intervention groups
In this study, patients with overactive bladder underwent cystocele repair. Before, one and six months after the intervention, bladder function is checked.
Main outcome variables
Urine urgency; Frequent urination; Urgent incontinence; Genital pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201108049307N1**
Registration date: **2020-12-18, 1399/09/28**
Registration timing: **registered_while_recruiting**
Last update: **2020-12-18, 1399/09/28**
Update count: **0**
Registration date
2020-12-18, 1399/09/28

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-10-22, 1399/08/01
Expected recruitment end date
2021-06-20, 1400/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of bladder function in patients with overactive bladder after cystocele repair

Public title
Bladder function in patients with overactive bladder after cystocele repair
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Age 18 years and older Diagnosis of overactive bladder Frequent urination more than eight times a day Feeling of urinary urgency more than once a day Being married Satisfaction to participate in the study

Exclusion criteria:

Breastfeeding Pregnancy Use of contraceptive methods Anticholinergic contraindication Need for catheter Obstruction of bladder outlet History of genitourinary surgery

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq.

City

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Province

Isfehan

Postal code

8179964167

Approval date

2020-10-07, 1399/07/16

Ethics committee reference number

IR.MUI.MED.REC.1399.581

Health conditions studied

1

Description of health condition studied

Overactive bladder

ICD-10 code

N32.81

ICD-10 code description

Overactive bladder

Primary outcomes

1

Description

Urine urgency

Timepoint

Before, 1 month and 6 months after the intervention

Method of measurement

Visual Analogue Scale

2

Description

Frequent urination

Timepoint

Before, 1 month and 6 months after the intervention

Method of measurement

Visual Analogue Scale

3

Description

Urgent incontinence

Timepoint

Before, 1 month and 6 months after the intervention

Method of measurement

Visual Analogue Scale

4

Description

Genital pain

Timepoint

Before, 1 month and 6 months after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients with overactive bladder underwent cystocele repair. Before, one and six months after the intervention, bladder function is checked.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital of Isfahan
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Shekofeh Gholi Pour
Position
Resident
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available