

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Name

Shekoofeh Gholipour nouroozi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5264 0795

Email address

behnammokhtari630@gmail.com

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

Isfahan

Province

Isfahan

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

Maryam Hajhashemi

Street address

Department of Obstetrics and Gynecology, Shahid Beheshti Hospital, Motahhari Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3234 6338

Email

m_hajhashemy@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

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

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Shahid Beheshti Hospital, Motahhari Street

City

Hsfahan

Province

Isfahan

Postal code

8491875893

Phone

+98 31 3234 6338

Email

Behnammokhtari630@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Hajhashemi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Shahid Beheshti Hospital, Motahhari Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3234 6338

Email

m_hajhashemy@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shekoofeh Gholi pour

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Department of Obstetrics and Gynecology, Shahid
Beheshti Hospital, Motahhari Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3234 6338

Email

Behnammokhtari630@gmail.com

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