

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the success of endoscopic repair of transurethral vesicovaginal fistula after hysterectomy

Protocol summary

Study aim

The aim of this study is to evaluate the success of endoscopic transurethral repair of vesicovaginal fistula following hysterectomy.

Design

This study is a clinical trial with an intervention group in which 10 patients in the intervention group undergo surgery.

Settings and conduct

This study is performed in Al-Zahra and Khorshid hospitals. Patients are placed in the lithotomy position. First, a cystoscopy is performed, and the location and size of the fistula and the distance of the fistula from the bladder neck are examined and recorded. The urethra is then dilated to 30 French, and the implant sheet is shortened to 30 French. Vicryl 2-0 thread, the end of which is tied in a loop, enters the bladder through an amplitude sheet. In the next step, the nephroscope enters the bladder through an amplitude sheet. The fistula is repaired using a 3 mm endoscopic needle. For repair with a distance of 5 mm from the edges of the fistula with a depth of 3 mm from the mucosa of the sutures is applied continuously. The first knot is made by passing the needle through the created loop. For the last knot, two ends of the thread are tied outside the bladder, and the knot is brought to the place of repair inside the bladder.

Participants/Inclusion and exclusion criteria

In this study, patients are selected from all women who have vesicovaginal fistula after hysterectomy. Patients with passing more than a month of the onset of incontinence, fistula diameter more than 2 cm, multiple fistulas, vesicovaginal fistula recurrence history, radiation history, concomitant existence, and ureterovaginal or urethrovaginal fistula are excluded.

Intervention groups

In the intervention group, patients' vesicovaginal fissures are repaired by an endoscopic transurethral method.

Main outcome variables

operation time; success rate; readmission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150420021869N3**

Registration date: **2021-07-18, 1400/04/27**

Registration timing: **prospective**

Last update: **2021-07-18, 1400/04/27**

Update count: **0**

Registration date

2021-07-18, 1400/04/27

Registrant information

Name

Farshad Gholipour

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

f-gholipour@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the success of endoscopic repair of transurethral vesicovaginal fistula after hysterectomy

Public title

Endoscopic repair of transurethral vesicovaginal fistula

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with vesicovaginal fistula after hysterectomy

Exclusion criteria:

Passing more than a month of the onset of incontinence
Fistula diameter more than 2 cm Multiple fistulas
Vesicovaginal fistula recurrence history Radiation history
Existence of concomitant ureterovaginal or urethrovaginal fistula

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

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 St, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.MUI.MED.REC.1400.231

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

vesicovaginal fistula

ICD-10 code

N82.0

ICD-10 code description

Vesicovaginal fistula

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

success rate

Timepoint

7 and 21 days after surgery

Method of measurement

history and physical examinaion

2**Description**

operation time

Timepoint

At the start and end of operation

Method of measurement

hour

3**Description**

readmission

Timepoint

until 21 days after sugery

Method of measurement

history

Secondary outcomes

empty

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

Intervention group: patients undergo endoscopic transurethral repair of vesicovaginal fistula.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital
Full name of responsible person
Farshad Gholipour
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Sofeh St
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2

Recruitment center

Name of recruitment center
khorshid hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
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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
Farshad Gholipour
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Urology
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Person responsible for updating data**Contact****Name of organization / entity**

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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 more information

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

There is no more information

When the data will become available and for how long

There is no more information

To whom data/document is available

There is no more information

Under which criteria data/document could be used

There is no more information

From where data/document is obtainable

There is no more information

What processes are involved for a request to access data/document

There is no more information

Comments