

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Investigating the effectiveness of High Intensive Focused Ultrasound (HIFO) in the treatment of urinary and fecal symptoms caused by rectocele and cystocele

Protocol summary

Study aim

Determining the effectiveness of High Intensive Focused Ultrasound (HIFO) in the treatment of pain caused by rectocele and cystocele

Design

A clinical trial with a control group with parallel groups, no-blinded, randomized on 100 patients and randomization via random number table.

Settings and conduct

The study was conducted in 1401 in Isfahan city. People are randomly placed in one of the two groups of Kegel and Haifu exercises, and the patients' symptoms and their condition are evaluated in two and six months. Kegel exercises are explained orally to the patients and they will practice 3 times a day for six months. 4.5 mm cartridge is also used for Hifo. For shots, the area from the end of the vagina to the front is divided into 3 parts and shots are taken at intervals of 2.5 cm between each line and less than 1 mm between each shot. The frequency of the device for the 4.5 mm cartridge is 4 MHz.

Participants/Inclusion and exclusion criteria

The inclusion criteria are women aged between 18 and 60 who have symptomatic grade 1 and 2 rectocele and cystocele. Exclusion criteria are people who do not consent to participate in the study

Intervention groups

HIFU and Kegel

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160521027998N10**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

Registration date

2023-04-17, 1402/01/28

Registrant information

Name

Maryam Hajhashemi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 6578

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of High Intensive Focused Ultrasound (HIFO) in the treatment of urinary and fecal symptoms caused by rectocele and cystocele

Public title

Hifo effect in rectocele and cystocele

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

grade 1 and 2 rectocele and cystocele

Exclusion criteria:

lack of consent

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done with the help of a random number table, in the order in which people entered the study, with the help of a random number table, they were assigned a number.

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 isgahan university of medical science

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2022-08-23, 1401/06/01

Ethics committee reference number

IR.MUI.MED.REC.1401.211

Health conditions studied

1

Description of health condition studied

Rectocele and Cystocele

ICD-10 code

N81.1

ICD-10 code description

Cystocele

2

Description of health condition studied

Rectocele

ICD-10 code

N81.6

ICD-10 code description

Rectocele

Primary outcomes

1

Description

pain

Timepoint

2 week.2 month, 6 month

Method of measurement

visual analogue scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: HIFU. In the treatment in this study, HIFU device is used using a 4.5 mm cartridge that penetrates to the fascia and can strengthen the pelvic muscles, and the energy produced is 1.5 joules. To shoot, the area from the end of the vagina to the front is divided into 3 parts, and shots are taken at intervals of 2.5 cm and less than 1 mm between each shot in each line. The frequency of the device for the 4.5 mm cartridge is 4 MHz. Two weeks, two months and six months later, patients are visited.

Category

Treatment - Devices

2

Description

Intervention group: Kegel exercises. Kegel exercises are explained orally to the patients and the patients will practice three times a day for up to 6 months. The way to follow up the exercises in the follow-up sessions will be two weeks, two months and six months later.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Maryam Hajheshemy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Amir Rahimi

Street address

Hezar Jarib street,

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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

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Maryam Hajhashemi

Position

associated professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Maryam Hajhashemi

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared after de-identification
When the data will become available and for how long
1402
To whom data/document is available
academic institutes
Under which criteria data/document could be used
academic researches
From where data/document is obtainable
dr. Maryam hajhashemi. 09132137267
What processes are involved for a request to access data/document
all application will be reviewed up to 1 month
Comments