Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Hajihashemi

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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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 comittee of isgahan university of medical science
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
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 Cyctocele
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

Rehabilitation

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Maryam Hajihashemi

Position
associated professor

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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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