

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of efficacy of preoperative and postoperative biofeedback therapy before sphinctroplasty- levatorplasty for fecal incontinence management due to obstetric trauma

Protocol summary

Summary

The women who suffering of fecal incontinence after normal vaginal delivery (NVD) that need surgical intervention depend on anal manometry and endoanal sonography. The patients have fecal incontinence after first NVD are going to refer to colorectal clinic of shahid faghihi hospital. exclusion criteria including: without post history of gas, stool or urinary incontinence, past medical history of diabetes melitus, musculo-skeletal disorders, previous pelvic or perineal surgery, COPD, ascites, intalented to learn biofeedback therapy. inclusion criteria: women with fecal incontinence after first NVD between 20 - 40 years old lady, wexner>10, decrease manometry below 30% normal and disruption of anterior part of external sphincter in sonography evaluation more than 90 degree. The patients will separate in 3 groups including 10 persons by randomization; then in group A the patients underwent sphinctroplasty-levatorplasty surgery. In group B, after sphinctroplasty-levatorplasty surgery, biofeedback therapy are going to do for 6 month. In group C at first, 3 month pre operation and 6 month post operation biofeedback therapy will perform; then after one & three months the patients will be evaluated again & wexner form will be completed by colorectal surgeon. Six months after operation, wexner, manometry & endo anal sonography will be done again and the patients are going to be evaluated. The manometry & endoanal sonography will performed by colorectal surgeon.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206039936N1**

Registration date: **2012-08-22, 1391/06/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-22, 1391/06/01

Registrant information

Name

Leila Ghahramani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1623 5586

Email address

lghahraman@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-07-31, 1391/05/10

Expected recruitment end date

2013-01-29, 1391/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of preoperative and postoperative biofeedback therapy before sphinctroplasty- levatorplasty for fecal incontinence management due to obstetric trauma

Public title

Effect of biofeedback therapy with surgery in management of fecal incontinence

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: women with fecal incontinence after first NVD between 20 – 40 years old lady; wexner>10; decrease manometry below 30% normal and disruption of anterior part of external sphincter in sonography evaluation more than 90 degree. Exclusion criteria: history of gas, stool or urinary incontinence; past medical history of diabetes melitus, musculo-skeletal disorders, previous pelvic or perineal surgery, COPD, ascites, intalented to learn biofeedback therapy.

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences Ethics Committee

Street address

Shahid Faghihi hospital

City

Shiraz

Postal code

7134844119

Approval date

2012-01-08, 1390/10/18

Ethics committee reference number

90-01-01-3247

Health conditions studied

1

Description of health condition studied

Fecal incontinence

ICD-10 code

R15

ICD-10 code description

Faecal incontinence

Primary outcomes

1

Description

Fecal incontinence

Timepoint

Before surgery, one, three, six months post operation

Method of measurement

Wexner, anal manometry, endoanal sonography

Secondary outcomes

1

Description

Improvement in manometry and endoanal sonography

Timepoint

Pre operation and six months post operation

Method of measurement

Manometry score and external sphincter degree in endoanal sonography evaluation

Intervention groups

1

Description

Patients who undergo sphincteroplasty-levatorplasty; control group

Category

Treatment - Surgery

2

Description

Patients who would be train to do post operation biofeedback therapy to six months after surgery.

Category

Rehabilitation

3

Description

Patients who would be train to do biofeedback therapy 3 months pre operation till six months post operation.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Colorectal surgery clinic, Shahid Faghihi hospital

Full name of responsible person

Dr Leila Ghahramani

Street address

Shahid Faghihi hospital

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Office of Research and Consultative Collaboration

Street address

Shiraz University of Medical Sciences

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Leila Ghahramani

Position

Colorectal surgery fellowship - assistant professor

Other areas of specialty/work

Street address

Shahid Faghihi hospital

City

Shiraz

Postal code

7134844119

Phone

+98 71 1230 6972

Fax

+98 23 31006

Email

leila_ghahramani@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz university of medical sciences

Full name of responsible person

Dr Leila Ghahramani

Position

colorectal flowship- assistant professor

Other areas of specialty/work

Street address

Shahid Faghihi hospital

City

Shiraz

Postal code

7134844119

Phone

+98 71 1230 6972

Fax

+98 23 31006

Email

leila_ghahramani@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Leila Ghahramani

Position

colorectal flowship- assistant professor

Other areas of specialty/work

Street address

Shahid Faghihi hospital

City

Shiraz

Postal code

7134844119

Phone

+98 71 1230 6972

Fax

+98 23 31006

Email

leila_ghahramani@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty