

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of the effect of pre-operative physiotherapy on quality of life and complications of colporrhaphy surgery in women suffering from pelvic organ prolapse

Protocol summary

Summary

The evidence to support physiotherapy treatment of pre and post-operative gynecological surgery patients is limited, and randomized trials in this area have been recommended. This randomized controlled trial investigated the effect of a pre operative physiotherapy-supervised pelvic floor muscle (PFM) training program in women undergoing surgery for prolapse. In this Randomized clinical trial, 70 patients with pelvic organ prolapsed will be enrolled, that be divided into two intervention and control groups. In the intervention group patients before surgery will be 10 sessions of physiotherapy and then will be surgery and in the control group Surgery will be performed for patients. Then the nagging symptoms of prolapsed including, sexual dysfunction, urinary incontinence, dyspareunia measured and compared between the two groups. Also the quality of life of patients in both groups using the SF-36 questionnaire will be evaluated and compared. This study is aimed at the investigation of the effect of physiotherapy prior to surgery on therapy treatment in women diagnosed with mediocre/severe pelvic prolapse who under go surgery. If the effect of physiotherapy on treatment results is positive, it can be suggested along other necessary measures in these patients

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201188772N1**
Registration date: **2013-03-08, 1391/12/18**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-08, 1391/12/18

Registrant information

Name

Tahereh Mahmoodvand

Name of organization / entity

Hamedan University Medicine of Scinces

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of pre-operative physiotherapy on quality of life and complications of colporrhaphy surgery in women suffering from pelvic organ prolapse

Public title

Effectiveness of physiotherapy in pelvic organ prolapsed treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Patients with moderate pelvic organ prolapse candidate for colporrhaphy surgery; Patients with severe pelvic organ prolapse candidate for colporrhaphy surgery . Exclusion criteria: diabetes; obesity; urinary tract infection; genital cytology grade 1 and 4; prolapsed uterus; vaginal delivery with forceps and vacuum; history of fetal macrosomia, multiple pregnancy; history of surgery on the muscles and pelvic viscera

Age

From **20 years** old to **59 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Hamedan University of Medical Sciences

Street address

Hamadan University of Medical Science, Mhdiye Blvd

City

Hamedan

Postal code

3519638686

Approval date

2011-12-17, 1390/09/26

Ethics committee reference number

3266/7/70/16/د/پ

Health conditions studied

1

Description of health condition studied

pelvic organs prolapse

ICD-10 code

N81

ICD-10 code description

Female genital prolapsed

Primary outcomes

1

Description

Quality of life

Timepoint

Three months after surgery

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Sexual Dysfunction

Timepoint

Three months after surgery

Method of measurement

Questionnaire

2

Description

Urinary incontinence

Timepoint

Three months after surgery

Method of measurement

Questionnaire

3

Description

Dysparunia

Timepoint

Three months after surgery

Method of measurement

Questionnaire

Intervention groups

1

Description

intervention group in 10 sessions of physiotherapy is done with the same technique before surgery.

Physiotherapy is performed by a chiropractor with a similar technique and in 10 sessions.

Category

Treatment - Other

2

Description

Control group without any intervention undergo colporrhaphy surgery.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Mahnaz Yavangi

Street address

Fatemieh Hospital, Pasdaran avenue

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan Univesity of Medical Sciences

Full name of responsible person

Heydar Tavillani

Street address

Mhdiye Blvd, Hamadan University of Medical Sciences

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamadan Univesity 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

Hamadan University of Medical Sciences

Full name of responsible person

Tahereh Mahmoodvand

Position

Resident of Surgical Obstetrics and Gynecology

Other areas of specialty/work

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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