

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Study of efficacy of injectable bulking agent in low anal sphincter tonosity after surgical intervention for rectal prolapse

Protocol summary

Summary

The object of this one center study is to determine the effect of injectable bulking agent on fecal incontinence after surgical intervention for rectal prolapse. 50 patients suffering from fecal incontinence after surgery for rectal prolapse will be enrolled to study and based on lottery will be divided into two equal groups of case and control. Important inclusion criteria is low anal tonosity ; exclusion criteria is sphincter gap >180 degree & concurrent perianal disease. Endoanal ultrasound and anal manometry (pressure at rest and squeeze) will be performed. According to Wexner table (Cleveland Clinic Florida Incontinence Score) fecal incontinence will be record (from 0 to 20). Case group receives injectable bulking agent (5cc) sub mucosally. Active ingredient is polyacrylatepolyalcohol copolymer. Anal Manometry and endosonography will be carried out at the end of the first & the sixth month after the injection as well as score of incontinence will be measured. In the control group , endosonography and anal manometry and scoring of fecal incontinence will be performed at the same time and the results will record

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092124104N2**

Registration date: **2015-11-05, 1394/08/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-11-05, 1394/08/14

Registrant information

Name

Rezvan Mirzaei

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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mirzaei.r@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of efficacy of injectable bulking agent in low anal sphincter tonosity after surgical intervention for rectal prolapse

Public title

Effect of bulking agent on fecal incontinence

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: history of surgical intervention for rectal prolapse; fecal incontinence; no response to medical treatment; low tone anal sphincter exclusion criteria: anorectal malignancy; concurrent perianal disease (abscess, fistula, sepsis); anal sphincter defect >90 degree; sphinctroplasty; IBD; radiation;

psychological & cognitive problem

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Iran University of Medical Sciences

Street address

Hemmat high way

City

Tehran

Postal code**Approval date**

2015-09-07, 1394/06/16

Ethics committee reference number

IR.IUMS.REC.1394.25892

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

fecal incontinence

ICD-10 code

R15

ICD-10 code description

fecal incontinence

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

fecal incontinence

Timepoint

before , 1month ,6 months after injection

Method of measurement

wexner score

Secondary outcomes**1****Description**

correction of anal sphincter

Timepoint

before intervention , 1 &6 mounth after

Method of measurement

observation of ultrasonic scan

2**Description**

pressure of anal sphincter

Timepoint

before intervention , 1 &6 mounth after

Method of measurement

anal manometry

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

case group: Exantia injected single dose, submucosally
5cc in anal canal.

Category

Treatment - Drugs

2**Description**

control group: no treatment

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hazrat-e Rasool General Hospital

Full name of responsible person

Mirzaei Rezvan

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Hazrat-e Rasool General Hospital, Niyayesh St.,
Satarkhan St.,

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Javadmusavi Seyyedali

Street address

Shahid Hemmat highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

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Full name of responsible person

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Position

associated profossore

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