

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Randomized Double-blind Placebo Controlled Trial of Topical Platelet Lysate hydrogel in patients with anal fissure referee to colorectal research center of shiraz medical university of medical sciences.

Protocol summary

Summary

Anal fissure is a tear or crack in the distal anal canal that is associated with pain. It usually involves the epithelium, but it may involve the whole of anal mucosa in long term. The etiology of anal fissure is unknown, but the patients usually are accompanied by some risk factors such as constipation hypoxia increase sphincter pressure inflammatory bowel disease, malignancies, systemic disorders and sexual associated trauma. Platelet lysate hydrogel is hemoderivative pharmaceutical formulation that contains plenty of growth factors. These growth factors can induce tissue regeneration and revascularization and fibroblast proliferation. These processes will conduce toward enhancing collagen synthesis especially in damaged tissues. This study is aimed to evaluating the probability of platelet lysate hydrogel effectiveness in treatment of disease or retardation the development of the disease in anal fissure patients. Patients with chronic and acute anal fissure will be randomized into A and B groups. Group A will receive platelet lysate hydrogel and Rectol® and group B will receive placebo and Rectol®. Both groups will be evaluated by one colorectal surgeon that will blind to this Study. All the patients will be followed and evaluated after two weeks. Statistical analysis will be conducted eventually.

General information

Acronym

Randomized Double-blind Controlled Trial of Topical Platelet Lysate hydrogel in patients wit

IRCT registration information

IRCT registration number: **IRCT201304079936N4**

Registration date: **2013-07-02, 1392/04/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-02, 1392/04/11

Registrant information

Name

Leila Ghahramani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1623 5586

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-02-03, 1391/11/15

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized Double-blind Placebo Controlled Trial of Topical Platelet Lysate hydrogel in patients with anal fissure referee to colorectal research center of shiraz medical university of medical sciences.

Public title

Randomized Double-blind Placebo Controlled Trial of Topical Platelet Lysate hydrogel in patients with anal fissure referee to colorectal research center of shiraz medical university of medical sciences.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:1)Patient with acute and chronic anal fissure. 2) Patient without previous history of peri-anal fistula. 3) Patient without previous history of peri-anal abscess. 4) Patient without previous history of IBD, radiation, STD, TB Chemotherapy. 5) Patient without previous history of hemorrhoidectomy or peri-anal procedure. 6) Patient without previous history of migraine. 7) Patient without previous history of no pregnant. 8) Patient without previous history of anterior or posterior midline fistula. 9) Patient without previous history of IHD.

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

There is significant differentiation between sphincter pressure in male and female therefore, management response in male and female will be are different as little then this study will be perform in female participantant .

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences

City

Shiraz

Postal code

Approval date

2012-10-08, 1391/07/17

Ethics committee reference number

675

Health conditions studied

1

Description of health condition studied

Fissure

ICD-10 code

K60

ICD-10 code description

Fissure and fistula of anal and rectal regions

Primary outcomes

1

Description

Treatment of fissure

Timepoint

Two weeks after initial treatment

Method of measurement

Exam by colorectal surgeon and complete the form

Secondary outcomes

empty

Intervention groups

1

Description

The rectul drug will be used once daily in control group.

Category

Treatment - Drugs

2

Description

the platelet gel will be used once daily transrectaly in Intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Surgical Clinic of Shiraz University of Medical Sciences

Full name of responsible person

leila ghahramani, Assistant Professor of surgery

Street address

colorectal recerch center, shiraz univercity of medical scinces

City

shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vice-Chancellery of Research, Dr Gholamreza Hatam

Street address

Shiraz university of pharmacy

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 pharmacy, Shiraz University of Medical Sciences

Full name of responsible person

Akram Jamshidzadeh, pharm.D PhD

Position

Professor of Pharmacology

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Person responsible for scientific inquiries

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Person responsible for updating data

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doctor

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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