

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effect of amniotic membrane graft on wound healing process and decrease complications in patient who undergone anal fistulotomy

Protocol summary

Summary

Anal fistula is a linkage between skin and anal canal. the most common cause of fistula is abscess formation in the anal crypts. surgery is the best treatment for symptomatic anal fistula. if anal fistula left untreated can cause recurrent abscess formation. Surgical wound complications include pain, itching, discharge and infections. So employing methods that can accelerate wound healing has a significant impact on patient quality of life. Amniotic membrane transplantation is an idea for this purpose. Amniotic membrane transplantation have been used in various treatment such as adhesions resulting from surgery, corneal surface reconstruction, repair of injured tendons, ... In recent years several studies regarding the use of amniotic membrane as a biological dressing especially in the treatment of burns is published. Amniotic membrane has several advantages such as availability, low immunogenicity, high potency of differentiation. therefore, further research to evaluate the effect of biological dressings especially amniotic membrane for treatment of anal fistula is reasonable.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310219936N6**
Registration date: **2013-11-15, 1392/08/24**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-15, 1392/08/24

Registrant information

Name

Leila Ghahramani

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences

Expected recruitment start date

2012-07-10, 1391/04/20

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of amniotic membrane graft on wound healing process and decrease complications in patient who undergone anal fistulotomy

Public title

Evaluation the effect of amniotic membrane graft on wound healing process and decrease complications in patient who undergone anal fistulotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18-65 years old; low type

fistula; first time to be operated. Exclusion: history of TB and ; history of previous fistula operation; high type fistula; immunosuppression; proctitis; radiotherapy; complex fistula; stool or gas incontinency and egg allergy.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **85**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple 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

Street address

Shiraz

City

Shiraz

Postal code

Approval date

2012-05-17, 1391/02/28

Ethics committee reference number

91-01-01-5270

Health conditions studied

1

Description of health condition studied

Anal fistula

ICD-10 code

K60.3

ICD-10 code description

Anal fistula

Primary outcomes

1

Description

Post operation complication

Timepoint

1, 3, 7, 21, 28th days of post operation

Method of measurement

Evaluation of score of pain after surgery in both groups with visual analog scale (VAS)

Secondary outcomes

1

Description

Discharge

Timepoint

1, 3, 7, 21 and 28th days of post operation

Method of measurement

Subjectively

2

Description

Itching

Timepoint

1, 3, 7, 21 and 28th days of post operation

Method of measurement

Subjectively no variable

Intervention groups

1

Description

In group B: Amniotic membrane is not the only place marsupialization thread Monocryl (0-4).

Category

Treatment - Surgery

2

Description

In group A : Amniotic membrane graft group patients using 0-4 suture is Monocryl (amniotic membrane on the bottom layer to the edges of the fistula tract located Monocryl thread is fixed)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Surgical Clinic of Shiraz University of Medical Sciences

Full name of responsible person

Dr Leila Ghahramani- Assistant professor of General Surgery

Street address

Colorectal Research Center, Faghihi hospital, Shiraz,
Iran

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholam Reza Hatam

Street address

Shiraz University of Medical Sciences

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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**

Colorectal Research Center, Shiraz university of
medical sciences

Full name of responsible person

Dr Alireza Safarpour

Position

MD, MPH

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Position

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Shiraz University of Medical Sciences, Colorectal
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Full name of responsible person

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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