

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Assessment of the amniotic membrane effect on healing of anal fissure wound after surgery

Protocol summary

Study aim

Determining the effect of amniotic membrane on anal fissure wound healing

Design

This randomized- controlled parallel, open label clinical trial study will be conducted on 110 patients. the randomization will be done using Random allocation software.

Settings and conduct

In this open label clinical trial, patients with anal fissure wound will be enrolled. The patients will be divided randomly into two groups. In the intervention group, in addition to standard sphincterotomy surgery, two Cm2 of amniotic membrane prepared from the stem cell center of the Tehran University will be sutured to the margin of the anal fissure wound. In the control group, only standard sphincterotomy surgery will be performed.

Participants/Inclusion and exclusion criteria

This study will be conducted on patients suffering anal fissure. The exclusion criteria will be including Inflammatory bowel disease; past medical history of previous anal surgeries; BMI>30 kg/m2; and autoimmune diseases.

Intervention groups

In the intervention group, in addition to standard sphincterotomy surgery, two Cm2 of amniotic membrane prepared from the stem cell center of the Tehran University will be sutured to the margin of the anal fissure wound. In the control group, only standard sphincterotomy surgery will be performed.

Main outcome variables

The wound healing rate; anal pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210919052515N3**

Registration date: **2022-02-13, 1400/11/24**

Registration timing: **prospective**

Last update: **2022-02-13, 1400/11/24**

Update count: **0**

Registration date

2022-02-13, 1400/11/24

Registrant information

Name

Naser Masoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3337 9924

Email address

masoudi.n@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the amniotic membrane effect on healing of anal fissure wound after surgery

Public title

Assessment of the amniotic membrane effect in anal fissure wound

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with anal fissures Patients with no recovery despite treatment with fiber, topical ointment and hot tub for more than 3 weeks Having pain during defecation

Exclusion criteria:

History of inflammatory bowel disease Past medical history of previous anal surgeries BMI>30 kg/m2 Autoimmune diseases

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 110

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into intervention and control groups using block randomization based on generated numbers by random allocation software. Thus, in this software, first the number of groups and the total number of the sample size will be entered, and then in the block section, the Block randomization method will be selected. Patients will be allocated in intervention or control groups based on generated numbers.

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

Ethics Committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Resalat street, Jihad Blvd., Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2021-11-10, 1400/08/19

Ethics committee reference number

IR.UMSU.REC.1400.354

Health conditions studied

1

Description of health condition studied

Fissure wound

ICD-10 code

K60

ICD-10 code description

Fissure and fistula of anal and rectal regions

Primary outcomes

1

Description

Wound healing

Timepoint

1, 2, 3 and 4 weeks after surgery

Method of measurement

Clinical examination

2

Description

Duration of pain

Timepoint

Up to 4 weeks after surgery

Method of measurement

The number of days with pain

Secondary outcomes

1

Description

Wound infection

Timepoint

1, 2, 3 and 4 weeks after surgery

Method of measurement

Clinical examination

2

Description

Pruritus of wound

Timepoint

1, 2, 3 and 4 weeks after surgery

Method of measurement

Clinical examination

Intervention groups

1

Description

Intervention group: in addition to standard sphincterotomy surgery, two Cm2 of amniotic membrane prepared from the stem cell center of the Tehran University will be sutured to the margin of the anal fissure wound

Category

Treatment - Other

2

Description

In the control group, only standard sphincterotomy surgery will be performed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr. Naser Masoudi

Street address

Imam Khomeini hospital., Ershad Ave., Modarres Blvd., Urmia., Iran.

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masoudi.n@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Saber Gholizadeh

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Urmia University of Medical Sciences, Resalat street, Jihad Blvd., Urmia, Iran.

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gholizadeh.s@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Naser Masoudi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of patient information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the study will be published as an article.

When the data will become available and for how long

After publishing the article

To whom data/document is available

researchers

Under which criteria data/document could be used

The results will be published as an article and the data will not be published.

From where data/document is obtainable

corresponding author

What processes are involved for a request to access data/document

By email address of the corresponding author

Comments