Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 dome 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, Jahad 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, Jahad 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 updating data

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Oroumia University of Medical Sciences
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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