Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Comparing the efficacy of amniotic membrane allograft with conventional dressing methods on the duration of treatment of pilonidal sinus patients

Protocol summary

Study aim

Evaluating the effect of amniotic membrane allograft on the duration of treatment of pilonidal sinus patients compared to conventional dressing methods

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 30 patients. The table of random numbers from www.randomization.com was used for randomization.

Settings and conduct

This study will be conducted in the surgery department of Qaem Hospital in Mashhad. 30 patients with pilonidal sinus are selected based on specific inclusion criteria and randomly divided into two intervention and control groups. The surgical procedure will be the same in both groups. In the control group, patients are subjected to routine care for secondary wound healing after surgery. In the intervention group, one week after surgery, patients undergo amniotic membrane transplantation and monitoring. At the end of the study, the two groups will be compared in terms of the duration of wound healing until the complete formation of the epithelium. The allocator of the sample to the groups and the data analyzer will be unaware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years old with the first episode of Pilonidal sinus disease one week after surgery, having Surgical wounds with a size of 4 x 4 cm and larger without infection. Absence of sinus abscess and absence of underlying chronic diseases that impair wound healing, such as diabetes and connective tissue diseases, and not using glucocorticoid during the study period.

Intervention groups

In the intervention group, a skin patch of amnion membrane ill be placed on the wound one week after surgery. In the control group, the usual dressing methods are used.

Main outcome variables

The time required for wound healing until the complete formation of epithelium without evidence of separation of wound edges and necrosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221008056113N1**
Registration date: **2023-07-13, 1402/04/22**
Registration timing: **prospective**

Last update: **2023-07-13, 1402/04/22**
Update count: **0**

Registration date

2023-07-13, 1402/04/22

Registrant information

Name

Mohammad Etezadpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-05-14, 1403/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of amniotic membrane allograft with conventional dressing methods on the duration of treatment of pilonidal sinus patients

Public title

Evaluation of the effect of amniotic membrane allograft on duration and costs of treatment in pilonidal disease compared with conventional methods

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years old with the first manifestation of pilonidal sinus disease one week after surgery Surgical wounds with a size of 4 x 4 cm and larger without infection

Exclusion criteria:

Pilonidal sinus with abscess formation Underlying chronic diseases that disrupt wound healing, such as diabetes and connective tissue diseases. Glucocorticoid consumption during the study period

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method was used, in which the patients were divided into 6 blocks, and then the list of blocks was written and numbers were assigned to them. Then a random number between 1 and 5 is selected and finally the treatment allocation list is determined based on the previous random numbers. The randomization unit is individual, and the randomization tool is a table of random numbers. The random sequence was created using the table of random numbers through www.randomization.com. The method of concealment is the allocation of sealed envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person allocating the sample to the groups and the person analyzing the data do not know the type of intervention. Regarding the type of intervention, the participants and the medical personnel taking care of them as well as the main researcher (surgeon) are aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Qaem hospital, Ahmad abad Ave, Mashhad Town

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699311

Approval date

2022-04-12, 1401/01/23

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.088

Health conditions studied

1

Description of health condition studied

Pilonidal sinus

ICD-10 code

L05.9

ICD-10 code description

Pilonidal cyst and sinus without abscess

Primary outcomes

1

Description

The time required for wound healing until the complete formation of the epithelium

Timepoint

After the initial visit one week after surgery, patients are examined two weeks later (i.e. the third week after surgery) and then weekly for 6 to 8 weeks (depending on the time required for wound healing).

Method of measurement

Examination of wounds is performed by a single experienced nurse and familiar with the wound healing process who will receive the necessary training.

Secondary outcomes

1

Description
Total cost for wound care, including the cost of purchasing dressings, antibiotics, and painkillers, as well as the cost of weekly visits.
Timepoint
At the end of the study
Method of measurement
All these costs are calculated regardless of insurance, and the patients will be asked at each visit and compared in two groups at the end of the complete recovery process.

Intervention groups

1

Description
Intervention group, in addition to the usual care of the wound, amnion-chorion dry sheets are used for dressing, and this product is provided under the brand name Life Cell from Bazar Teb Company. For this study, batch C4C6C7 of this
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Qaem hopital
Full name of responsible person
zahra kargar
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohammad Etezadpour
Street address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Mashhad University of Medical Sciences
Full name of responsible person
Asa Yousefi
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
Others
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Full name of responsible person
Asa Yousefi
Position

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Other areas of specialty/work

Others

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

After the completion of the study, the data related to the duration of wound healing in the study and control groups will be shared. A picture of the stages of wound healing in the intervention group will be taken at each visit and will be shared after making the people unidentifiable.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

access to these data will be allowed for surgeons and researchers in the field of wound healing, especially researchers who intend to conduct research on the effect of using amniotic membrane in other types of surgical wounds.

From where data/document is obtainable

The results of this research will be published on the website rpis.research.ac.ir. These results can also be achieved by calling one of the researchers of this project named Zahra Kargar and submitting a request.

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

The data can be obtained by registering in the rpis.research.ac.ir system and searching for the title of this research. You can also get these data by sending a massage to the number 00989215569742 and submitting your research project proposal.

Comments