

# 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](http://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 will 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)

##### Phone

+98 51 3514 5328

##### Email address

etezadpourm@mums.ac.ir

##### 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](http://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 hospital

#### Full name of responsible person

zahra kargar

#### Street address

Ahmad abad Blvd.

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9176699311

#### Phone

+98 51 3840 9642

#### Email

zahrakargar777@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Mohammad Etezadpour

#### Street address

Ghaem Hospital, Ahmad Abad Ave, Mashhad town

#### City

Mashhad

### Province

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+98 51 3840 9642

### Email

etezadpourm@mums.ac.ir

### 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

#### Street address

Ghaem Hospital, Ahmad Abad Ave, Mashhad town

#### City

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+98 51 3840 9642

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yousefia952@mums.ac.ir

## Person responsible for scientific 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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Ghaem Hospital, Ahmad Abad Ave, Mashhad town  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Asa Yousefi  
**Position**  
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9176699311  
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+98 51 3840 9642  
**Email**  
Yousefia952@mums.ac.ir

## 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](http://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](http://rpis.research.ac.ir) system and searching for the title of this research. You can also get these data by sending a message to the number 00989215569742 and submitting your research project proposal.

### Comments