

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparing the effectiveness and side effects of dressing with amniotic membrane and dressing with Vaseline gauze for secondary intention of finger tip lesions

Protocol summary

Study aim

The purpose of this study is to investigate the complications and efficiency of fingertip injury repair in the secondary repair method using petroleum jelly and amniotic dressing.

Design

The present clinical trial includes two groups of vaseline and amnion dressings and will be conducted in a non-randomized and double-blind manner. Allocation to groups will be done based on the opinion of the surgeon and 20 samples will be collected in each group

Settings and conduct

Patients referred to the emergency room after being screened according to the entry and exit criteria in the operating room, their wounds are washed and debrided, and according to the doctor's opinion, they are dressed with one of the vaseline or amniotic gauze dressings, and then on the 5th day, one month, and two months later.

They are examined in terms of main variables

Participants/Inclusion and exclusion criteria

The participants in this study are all the people who came to Hazrat Fatemeh Hospital with fingertip injuries and have an age range of 18 to 60 years. Participants who have a wound size of less than 3 cm and without tendon and bone damage are included in the study, and people who have an underlying disease such as connective tissue, diabetes, or autoimmune disease, or who take drugs that weaken the immune system, are excluded from the study

Intervention groups

After being transferred to the operating room by the doctor's diagnosis, after washing and debriding the wound, the patients were dressed with one of the vaseline and amniotic gauze dressings, and they were examined on the 5th day, one month, and three months after the operation, and their wound condition was classified according to the gauze dressing group.

Vaseline or amniotic fluid is checked and recorded

Main outcome variables

The degree of sensation, the degree of complications, the degree of skin color matching, the degree of epithelialization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230817059175N1**

Registration date: **2023-08-24, 1402/06/02**

Registration timing: **prospective**

Last update: **2023-08-24, 1402/06/02**

Update count: **0**

Registration date

2023-08-24, 1402/06/02

Registrant information

Name

Hamidreza Farhmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8871 7272

Email address

hamidreza.farhmand@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2024-02-29, 1402/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness and side effects of dressing with amniotic membrane and dressing with Vaseline gauze for secondary intention of finger tip lesions

Public title

Comparing the effectiveness and side effects of dressing with amniotic membrane and dressing with Vaseline gauze for secondary intention of finger tip lesions

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Fingertip injuries without tendon and bone damage The maximum extent of the injury is 3 cm

Exclusion criteria:

Terrestrial diseases such as connective tissue diseases, immunodeficiency, diabetes Taking immunosuppressive drugs Lesions larger than 3 cm Lesions with wound infection and tendon and bone damage

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

In the process of blinding, considering that the doctor chooses one of the dressings of vaseline and amnion gas according to his opinion, the patient is not aware of the type of dressing, also during the evaluation in the clinic, the person who records and evaluates the variables of the research is not aware of the type of dressing and Only the surgeon knows the type of dressing

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat highway

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2023-08-16, 1402/05/25

Ethics committee reference number

IR.IUMS.FMD.REC.1402.258

Health conditions studied**1****Description of health condition studied**

Fingertip injury

ICD-10 code

S60.10XD

ICD-10 code description

Contusion of unspecified finger with damage to nail, subsequent encounter

Primary outcomes**1****Description**

The range of feeling

Timepoint

The third day, one month and two months after surgery

Method of measurement

Using the 2PD test

2**Description**

The degree of epithelialization

Timepoint

The third day, one month and two months after surgery

Method of measurement

Observation

3**Description**

Complications

Timepoint

The third day, one month and two months after surgery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, after washing and wound debridement in the operating room, depending on the opinion of the surgeon, a dressing containing amniotic material will be used, and then several layers of dry gauze and bandage will be used on it, and then on the fifth day after the operation, the wound will be opened in the clinic and examined. will be

Category

Treatment - Other

2

Description

Control group: In this group, after washing and wound debridement in the operating room, depending on the opinion of the surgeon, a dressing containing Vaseline gauze will be used, and then several layers of dry gauze and bandage will be used on it, and then on the fifth day after the operation, the wound will be opened in the clinic and the wound will be examined. will be

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Fatemeh Hospital

Full name of responsible person

Hossein Akbari

Street address

Seyed Jamalodin Asadabadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Hamidreza Farhmand

Position

Special Assistant

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Hossein Akbari

Position
Associate professor

Latest degree
Subspecialist

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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 data file of the participants, including the type of dressing used and the examination of the variables, will be collected in an Excel file and will be kept in the department of the Clinical Development Research Center of the hospital, and if the researchers need this information, they will be allowed to use it with a license

When the data will become available and for how long

Researchers can access the information whenever they want with the permission from the vice president of research and having the code of ethics of the research project

To whom data/document is available

Researchers in the field of reconstructive plastic surgery and burns from all academic centers in the country

Under which criteria data/document could be used

In order to use or model the way of data collection in related studies and to have a code of study ethics

From where data/document is obtainable

To receive information, send your request to the email of the research center and receive the information. Email: office.amozesh@gmail.com

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

First, he submits his request and then the expert of the center requests the necessary documents to receive the data file. After sending the documents that have a related study and similar to the data file, the data file will be sent to the researcher

Comments