Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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
۱۴۴۹۶۱۴۵۳۵
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
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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
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Person responsible for scientific inquiries

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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