

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of repair of acute full-thickness defect wounds of the hand in repair with Alloderm compared to skin grafting

Protocol summary

Study aim

Comparison of repair with Eloderm and individual skin graft in terms of recovery time, cost, contouring and sensation

Design

Phase two on two groups of 25 people will be randomly randomized, one will be repaired with autograft and the other will be repaired with allograft. The study is one-sided blind and only the patients do not know about the type of surgery and treatment selected. Also, this study will be conducted with parallel groups.

Settings and conduct

Performing reconstructive surgery for hand injuries in patients referred to Hazrat Fatemeh Hospital. The selection of the type of repair is explained based on the random selection and will be based on a lottery, in one group the repair will be done with allograft from cadaver and in the other group, the repair will be done with the person's own full-thickness autograft. In this study, only the participants did not know about the type of surgery, and the researcher and evaluator of the information were aware of the type of surgery, so the study is single-blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: Complete skin damage of fingers and hand at volar or palmar level, People between 18 and 60 years old Exclusion criteria: People with a history of connective tissue disease and vascular collagen, People with a history of Steroid use, Smokers, Wounds with bone surfaces and open tendons

Intervention groups

In one group, repair is done with hypotenar full thickness autograft, and in the intervention group, repair is done using Eloderm dressing along with split thickness autograft, which is a thin layer of epidermis

Main outcome variables

Evaluation of patients in terms of sensation, graft contouring, skin color, recovery time, treatment cost and duration of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230219057450N1**

Registration date: **2023-02-25, 1401/12/06**

Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**

Update count: **0**

Registration date

2023-02-25, 1401/12/06

Registrant information

Name

Mohamad Mehran Aminifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8871 7272

Email address

aminimeehraan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-16, 1401/12/25

Expected recruitment end date

2023-08-16, 1402/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of repair of acute full-thickness defect wounds of the hand in repair with Alloderm compared to skin grafting

Public title

Comparison of repair of acute full-thickness defect wounds of the hand in repair with Alloderm compared to skin grafting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Complete skin damage of the fingers and hands at the volar or palmar level People between 18 and 60 years old

Exclusion criteria:

People with a history of connective tissue, collagen and scholar disease People with a history of steroid use Smokers Wounds with open bony and tendon surfaces

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we numbered 50 papers in a container that cannot be seen from the outside and assigned number 1 to 25 papers and number 2 to the other 25, then before each patient's surgery in the operating room, we took out a paper from the container. And based on number 1 (repair with Eloderm) or 2 (repair with patient's skin graft), we determine the type of operation

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is of a blind type, in which the patient is not aware of the study process and the placement of the study groups, but the researcher and evaluator of the information in the process of placement of people in the groups

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

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2023-02-15, 1401/11/26

Ethics committee reference number

IR.IUMS.FMD.REC.1401.656

Health conditions studied

1

Description of health condition studied

Patients with acute hand injuries

ICD-10 code

S69.8

ICD-10 code description

Other specified injuries of wrist and hand

Primary outcomes

1

Description

Recovery time

Timepoint

Immediately after surgery to six months after surgery

Method of measurement

Based on calendar days

Secondary outcomes

1

Description

Skin contouring

Timepoint

Three months and six months after surgery

Method of measurement

Based on qualitative skills

2

Description

Having sense

Timepoint

Three months and six months after surgery

Method of measurement

Direct assessment by pressure on the repair site

Intervention groups

1

Description

Intervention group: Treatment with Aloderm Split Graft

Category

Treatment - Surgery

2

Description

Control group: Treatment with one's own full-thickness autograft

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Fatemeh Hospital

Full name of responsible person

Mohamad Mehran Aminifard

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Seyed Jamalodin Asadabadi St.

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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?

No

Title of funding source

Hazrate Fatemeh Hospital

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

Mohamad Mehran Aminifard

Position

Specialist assistant

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Full name of responsible person

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Associate professor

Latest degree

Subspecialist

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

Specialist

Other areas of specialty/work

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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

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

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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 and the study protocol will be provided to the people after the study is done in the article and the final report of the thesis. Also, the informed consent form can be downloaded in the appendix of the thesis

When the data will become available and for how long

One year after the end of the study

To whom data/document is available

All researchers who have a topic similar to the current research work

Under which criteria data/document could be used

For modeling and guidance

From where data/document is obtainable

Public official Mohammad Mehran Amini Fard
aminimeehraan@gmail.com

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

After sending an email to the public official and mentioning the title of your research work, a response will be given within 2 weeks at the discretion of the public official

Comments