

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the Effect of Fibrin Glue Enriched with Platelets Compared to Stapler on the Faster Clinching of Skin Autografts Lesions in Burn Patients

Protocol summary

Study aim

Improvement of the patient's skin at the first, third and fourth month.

Design

Two arm parallel, individual randomised, single-blinded controlled trial.

Settings and conduct

This project will be conducted in the burn department of Imam Reza Hospital (p) in Mashhad. The data analyzer will be unaware of the group to which patients are assigned.

Participants/Inclusion and exclusion criteria

Patients with burns that need autograft will be included in the study. Patients with diabetes, collagen vascular disorders, taking anticoagulant drugs or corticosteroids or being allergic to local anaesthesia will be excluded.

Intervention groups

The fibrin glue, a biological surgical glue and a mixture of gelatin and ReCverin, will be evaluated in comparison to the stapler.

Main outcome variables

Percentage of improvement of lesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130819014404N3**

Registration date: **2019-04-28, 1398/02/08**

Registration timing: **prospective**

Last update: **2019-04-28, 1398/02/08**

Update count: **0**

Registration date

2019-04-28, 1398/02/08

Registrant information

Name

Majid Khadem-Rezaian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 9262

Email address

khademrm831@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Fibrin Glue Enriched with Platelets Compared to Stapler on the Faster Clinching of Skin Autografts Lesions in Burn Patients

Public title

Effect of fibrin glue enriched with platelets and stapler in burn patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who had burn injuries. Burn lesions that need graft.

Exclusion criteria:

Diabetes. Collagen vascular disease or hemorrhagic disorders. Consuming anticoagulants or steroids drugs. Being allergic to local anesthesia or Bacitracin. Patient dissatisfaction.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization using the table of random numbers which are palced in sealed opaque envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data analyser will be blinded to the study groups.

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

Ghoreishi Building, Before Golestan Crossroad, Daneshgah Ave., Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2018-04-11, 1397/01/22

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.009

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

Burns of head, face, and neck

ICD-10 code

T20

ICD-10 code description

Burn and corrosion of head, face, and neck

2**Description of health condition studied**

Burns of trunk

ICD-10 code

T21

ICD-10 code description

Burn and corrosion of trunk

3**Description of health condition studied**

Burns of shoulder and upper limb

ICD-10 code

T22

ICD-10 code description

Burn and corrosion of shoulder and upper limb, except wrist and hand

4**Description of health condition studied**

Burns of wrist and hand

ICD-10 code

T23

ICD-10 code description

Burn and corrosion of wrist and hand

5**Description of health condition studied**

Burns of lower limb

ICD-10 code

T24

ICD-10 code description

Burn and corrosion of lower limb, except ankle and foot

6**Description of health condition studied**

Burns of ankle and foot

ICD-10 code

T25

ICD-10 code description

Burn and corrosion of ankle and foot

7**Description of health condition studied**

Burns of multiple body regions

ICD-10 code

T29

ICD-10 code description

Burns and corrosions of multiple body regions

Primary outcomes

1

Description

The improvement of patients' skin

Timepoint

One, three and four weeks after surgery.

Method of measurement

Clinical evaluation

Secondary outcomes

1

Description

Condition of skin infection

Timepoint

One, three and four weeks after surgery

Method of measurement

Clinical evaluation and wound culture

2

Description

The condition of skin graft

Timepoint

At 8th week after surgery (followup)

Method of measurement

Clinical evaluation

Intervention groups

1

Description

Intervention group: Surgical biological adhesive; Fibrin glue which is produced by the Microwave Company of France and the Tisceon brand

Category

Treatment - Devices

2

Description

Control group: Stapler

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza (p) Hospital

Full name of responsible person

Dr. Seyed Hasan Tavooosi

Street address

Ibn Sina street, Imam Reza Sq., Mashhad

City

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Postal code

91379-13316

Phone

+98 51 3854 3031

Email

TavoosiH@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Ghoreishi Building, Before Golestan Crossroad,
Daneshgah Ave., Mashhad, Iran

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Postal code

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Email

TafaghodiM@mums.ac.ir

Grant name

Dr. Seyed Hassan Tavooosi

Grant code / Reference number

950681

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

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

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Hasan Tavousi

Position

Specialist of General surgery, fellowship of burn

Latest degree

Specialist

Other areas of specialty/work

Burn

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Imam Reza Hospital, Imam Reza Sq., Ibn Sina Ave.,

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Hasan Tavousi

Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

Clinical Study Report

When the data will become available and for how long

After finishing the study and publication of findings

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

Acquiring permission and coordination with primary researchers

From where data/document is obtainable

Dr. Daryoush Hamidi Alamdari (Email: HamidiAD@mums.ac.ir)

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

A written agreement from the Vice-Chancellor of Research of Mashhad University of Medical Sciences

Comments