

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of early excision and grafting versus delayed excision and grafting on restoring the functionality of deep burn-injured hands

Protocol summary

Study aim

The aim of this study was the comparison between two EEG and DEG procedures in restoring the functionality of burn hands after 1 and 3 months by Michigan Hand Questionnaire (MHQ).

Design

A double blind, randomized parallel clinical trial

Settings and conduct

Hands are common sites for the burn. Early excision and grafting (EEG) and delayed excision and grafting (DEG) of burn wounds decreases the hospital stay, hospital costs, and septic complications. This study compares these 2 methods in restoring the functionality of hands after 1 and 3 months by Michigan Hand Questionnaire (MHQ). This is the randomized double-blind clinical trial being performed from January 2013 to December 2015 on both hand burn who met inclusion criteria in Ghotbod hospital, Shiraz University of Medical Sciences, Shiraz, Iran. The study participants and the observers will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: patients with deep second and third-degree burn covering less than 50% of total body surface area (TBSA) and both hand burn with deep second degree burn with an age limitation of 15-70 years. Exclusion Criteria: elderly patients with comorbidity diseases, scars from previous burn injuries and having connective tissue disorders or burn as a component of multiple trauma, significant inhalation injury or need to intensive care, Left handed patients and also less than 10 hand finger burn.

Intervention groups

The patients were assigned to two study groups; the early excision and grafting (EEG) group before 6 days and the delayed excision and grafting (DEG) group in the second week.

Main outcome variables

Hand Function; pain, activity daily limitation, overall satisfaction; cosmetics

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141218020364N7**

Registration date: **2018-01-29, 1396/11/09**

Registration timing: **retrospective**

Last update: **2018-01-29, 1396/11/09**

Update count: **0**

Registration date

2018-01-29, 1396/11/09

Registrant information

Name

Mohammad Yasin Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3839 1385

Email address

karamiy@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2015-12-31, 1394/10/10

Actual recruitment start date

2013-01-11, 1391/10/22

Actual recruitment end date

2015-12-31, 1394/10/10

Trial completion date

empty

Scientific title

Effect of early excision and grafting versus delayed excision and grafting on restoring the functionality of deep burn-injured hands

Public title

Early Excision and Skin Grafting versus Delayed Skin Grafting effect on function in hand Deep Burns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Deep second and third-degree burns both hand burn with deep second degree burn age limitation of 15-70 years covering less than 50% of total body surface area (TBSA)

Exclusion criteria:

elderly patients with comorbidity diseases (diabetes Mellitus, chronic respiratory, cardiac and vascular diseases, hypertension) scars from previous burn injuries having connective tissue disorders burn as a component of multiple trauma significant inhalation injury or need to intensive care Left handed patients less than 10 hand finger burn

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **150**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

the random drawing of sealed envelopes (Computer-based table of randomization)

Blinding (investigator's opinion)

Double blinded

Blinding description

The study participants had know two types of common burn injuries treatment, But due to the dressing on the burn wound, they were not aware of the type of treatment we were used for them. The observer who completed the questionnaire did not know the study groups. The original researcher (burn surgeon) was aware of the study groups. The data analyzer was not known from the study groups. The safety committee and data monitoring were aware of 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 Shiraz University of Medical Sciences

Street address

Fakhrabad Street

City

Shiraz

Province

Fars

Postal code

987163854733

Approval date

2012-10-31, 1391/08/10

Ethics committee reference number

IR.SUMS.MED.REC.1394.90

Health conditions studied

1

Description of health condition studied

Deep Hand Burn

ICD-10 code

T23

ICD-10 code description

Burn and corrosion of wrist and hand

Primary outcomes

1

Description

Disabilities of hand

Timepoint

Patients were visited weekly in the first month and then every month for the next 3 months.

Method of measurement

Direct supervision by the surgeon and completed questionnaire (Michigan hand Q about the function of the hands, ADL, pain, daily activity limitation, scar formation and overall satisfaction in MHQ questionnaire).MHQ questionnaire filled at end of the first and third month.

Secondary outcomes

1

Description

Complication after surgery

Timepoint

3 month after surgery

Method of measurement

follow up by surgeon

Intervention groups

1

Description

Intervention Group 1 (Early Excision and Skin Grafting (EEG)): In the EEG group, the patients will be operating after being stabilized during the fifth or seventh day after the injury. In the operation room, under the sterile condition and after general anesthesia, upper extremity tourniquet will be used to decrease active bleeding. The dead tissue in deep burn hand skin will be debrided using Goulian knife; then, tissue viability will assess according to the amount of bleeding in the debrided tissues. The debrided area will then cover with a sheet of skin (0.3 mm thickness) and fixe with skin stapler. The dressing will be applied and all of the below mentioned postoperative steps for the DEG group will be used for the EED group. Short splitting will be applied on the hands until the first dressing change. Passive and active hand physiotherapy will start at the end of 7th day.

Category

Treatment - Surgery

2

Description

Intervention Group 2 (Delayed Excision Skin Grafting (DEG)): In the DEG group, the patients will operate after being stabilized (complete granulation tissue formation) after the first 14 days after injury. Daily dressing (twice a day) with topical antibiotics including silver sulfadiazine and mafenide acetate will use under a general surgeon supervision. The infected wound will be treated with intravenous antibiotics according to wound culture and antibiogram. In the operating room with an aseptic setting and under generalized anesthesia, the dead tissue (Scar) will be excised and debrided until reaching a proper bed for skin grafting (viable tissue). The debrided area will then cover with a partial thickness non-meshed (sheet) skin in use from the patient's healthy skin of the thighs at the same stage. The dressing will then remove on the 5th postoperative day unless signs of infection (such as abnormal discharge, high-grade fever, changes in general condition, etc.) will observe; their dressings will change sooner.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghotb-eddin Burn Center

Full name of responsible person

Mehdi Ayaz

Street address

Fakhrabad Street

City

Shiraz

Province

Fars

Postal code

987163854733

Phone

+98 71 3821 9638

Fax

+98 71 3821 7090

Email

ayazmahdi@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hashemi Seyed Basir

Street address

Vice-chancellor of Research, Shiraz University of Medical Sciences Shiraz

City

Shiraz

Province

Fars

Postal code

98713451978

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mehdi Ayaz

Position

Assistant Professor, General Surgeon

Latest degree
Specialist
Other areas of specialty/work
burn Surgery
Street address
Fakhrabad Street,
City
Shiraz
Province
Fars
Postal code
987163854733
Phone
+98 71 3821 9638
Fax
Email
ayazm@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mehdi Ayaz
Position
Assistant Professor, General Surgeon
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
Fakhrabad Street, Shiraz
City
Shiraz
Province
Fars
Postal code
987163854733
Phone
+98 71 3821 7090
Fax
Email
ayazm@sums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Yasin Karami
Position
General Surgeon
Latest degree

Specialist
Other areas of specialty/work
General Surgery
Street address
Faghihi Hospital, Department of surgery
City
Shiraz
Province
Fars
Postal code
987163854733
Phone
+98 71 3233 1006
Fax
Email
karamiy@sums.ac.ir
Web page address

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

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

all collected deidentified IPD data could be shared.

When the data will become available and for how long

12 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

data analysis in the systematic review is provided.

From where data/document is obtainable

all applicant should call the following number: Mehdi Ayaz; Burn and wound healing research center, Department of Surgery, Division of Burn and Reconstructive Surgery Shiraz University of Medical Sciences Shiraz, Iran. E-mail: ayazmahdi@yahoo.com
Postal address: 71339-75121 Tel number: 00989121085896.

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

After contacting the applicant and identifying the university identity and reviewing the application, the information will be e-mailed to him/her within a one-month period of time.

Comments