

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparative study of three methods of subcutaneous injection of insulin and amnion membrane and simple dressing with petroleum jelly in the repair of donor graft site in second and third degree burns in a period of one year in Taleghani Hospital of Ahvaz

Protocol summary

Study aim

Comparative study of three methods of subcutaneous injection of insulin, amniotic membrane and simple dressing with petroleum gauze in healing of donor graft site in second and third degree burn patients.

Design

People enter this study according to inclusion criteria. The study will be conducted on 120 patients in Ahvaz accident and burn hospital, and the intervention and control will be on one patient. A skin graft with a relative thickness of three sections of 5 x 9 cm in proximal 1.3, medial 1.3 and distal 1.3 of the wound will be randomly selected as case and control. subcutaneous insulin injection, amniotic membrane, simple dressing with petroleum gauze will be used as a dressing in order to compare these three methods in terms of donor site healing.

Settings and conduct

This study is an interventional study of the clinical trial type and the study site is Taleghani Burn Accident Hospital in Ahvaz, and the study subjects were 120 patients with second and third degree burns admitted to the hospital.

Participants/Inclusion and exclusion criteria

Second and third degree burn patients referred to Ahvaz Taleghani Burn Accident Hospital Patients aged 18 to 65 years were included in the study. Pregnant women, children, patients with underlying problems such as diabetes, cardiovascular problems, chronic kidney disease, chronic liver disease, vascular collagen diseases, and chronic skin diseases and receiving immunosuppressive drugs were excluded from the study

Intervention groups

Every Patients aged between 18 to 65 years old with second and third degree burns who need Split thickness skin graft (STSG) measured more than 15 cm

Main outcome variables

the area of the epithelialized area to follow the condition of the wound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240124060790N1**

Registration date: **2024-02-14, 1402/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-14, 1402/11/25**

Update count: **0**

Registration date

2024-02-14, 1402/11/25

Registrant information

Name

Ali Alizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3554 7996

Email address

alizadeh.ali@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-06, 1402/10/16

Expected recruitment end date

2025-01-05, 1403/10/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of three methods of subcutaneous injection of insulin and amnion membrane and simple dressing with petroleum jelly in the repair of donor graft site in second and third degree burns in a period of one year in Taleghani Hospital of Ahvaz

Public title

Effect of insulin injection, amniotic membrane and simple dressing with petroleum gauze in wound healing

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients between 18 to 65, Patients with second and third degree burn

Exclusion criteria:

Pregnant women Patients with underlying diseases such as Diabetes, chronic kidney disease, chronic liver disease, peripheral vascular disease, cardiovascular disease, collagen vascular disease, chronic skin disease ranging from autoimmune diseases to skin malignancies Heavy smokers Immunosuppressive medication users

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be conducted on 120 patients and the intervention and control will be on one patient. Considering the width of the dermatome at 9 cm and the length of the skin graft at least 15 cm with relative thickness, three sections of 5 x 9 cm in the proximal, medial and distal of the wound will be randomly selected as cases and controls. Insulin, placebo (normal saline serum) will be used subcutaneously and amnion membrane as a cover in the proximal, medial and distal areas of the mentioned wound. Description of how to randomize: Using the table of random numbers, case and control groups are randomly selected between proximal wound, medial wound and distal wound

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee Ahvaz Jondishapur University of Medical Sciences

Street address

Taleghani Burn hospital, Hejrat blvd., Padadshar 2 phase

City

Ahvaz

Province

Khuzestan

Postal code

6187954386

Approval date

2024-01-06, 1402/10/16

Ethics committee reference number

IR.AJUMS.REC.1402.532

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

2rd and 3rd degree burns

ICD-10 code

T20. 20XA-

ICD-10 code description

T20. 20XA: Burn of second degree of head, face, and neck, unspecified site, initial encounter. T21. 30XA : Burn of third degree of trunk, unspecified site, initial encounter. T86.822 : for skin graft (allograft)(autograft)

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

the area of the epithelialized area to follow the condition of the wound

Timepoint

مقاطع زمانی اندازه گیری: روز 7، 14 و 21 پس از انجام مطالعه

Method of measurement

Examining the area of the epithelialized area using ImageJ software

Secondary outcomes

empty

Intervention groups

1

Description

Description of the intervention in the case group: NPH insulin made by Elixir factory will be injected subcutaneously in a single dose with a concentration of 1 unit per milliliter with a dose of 2 cc in 10 points. After the intervention, the wounds of the dressing patients become clear. . In addition, blood sugar measurement will be done in order to prevent side effects such as hypoglycemia in patients before and after surgery

Category

Treatment - Surgery

2

Description

Control group:(Description of the intervention of the control group): The placebo in this study is normal saline serum, which will be injected subdermally in 10 points with a volume of 2 cc as a single dose like insulin. After the intervention, the wounds of the dressing patients become clear. On the 7th, 14th, and 21st days after the operation, the wound will be examined and a picture of the position will be taken

Category

Treatment - Surgery

3

Description

Intervention group: In the other intervention group, the amniotic membrane is used as a wound cover. On the 7th, 14th, and 21st days after the operation, the wound will be examined and a picture of the position will be taken.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani burn hospital,Ahvaz Jondishapur University of Medical Sciences

Full name of responsible person

Ali Alizadeh

Street address

Taleghani burn hospital, Hejrat blvd., Padadshahr 2 phase

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mahtab Farhadi

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Ahvaz Jundishapur University of Medical Sciences, Golestan Blv. Ahvaz.

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Email

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Web page address

http://www.ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Ali alizadeh

Position

Subspecialty Resident of plastic,burn and reconstructive surgery

Latest degree

Specialist

Other areas of specialty/work

Others

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Web page address<http://www.ajums.ac.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mahtab farhadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Web page address<http://jsmj.ajums.ac.ir>**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Ali alizadeh

Position

Subspecialty resident of plastic,burn and reconstructive surgery

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Web page address<http://ajums.ac.ir>**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Comparative data about three methods,subcutaneous insulin injection,amniotic membrane and simple dressing with petroleum gauze

When the data will become available and for how long

2024/1/6 to 2025/1/6

To whom data/document is available

Residents and lecturers University and researchers

Under which criteria data/document could be used

Access to these scientific materials for academic persons and researchers and students are completely free and for others only after request via email

From where data/document is obtainable

Access to information will be possible solely on email (alizadeh.ali@ajums.ac.ir)

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

| The information will be sent up to one month after receiving email

Comments

If you do not receive information up to a maximum of one month please send a message below
ali110alizadeh@yahoo.com