

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of local insulin injection on the healing process of split-thickness skin graft donor site in comparison to the placebo

Protocol summary

Study aim

Effect of topical insulin injection on wound healing of split-thickness skin graft donor site in comparison to the placebo

Design

This randomized double-blind clinical trial will be conducted on 30 samples (15 patients) in June 2019. Case and control groups in this study will be both in one patient. The proximal and distal parts of the wound will be selected randomly for injecting the drug or placebo.

Settings and conduct

This randomized double blind clinical trial will conduct in Razi hospital, Tehran. 15 patients will be enrolled in this study who have split-thickness skin graft donor site wound on the anterolateral of their thigh. The wound of every patient will be divided into two control and case segments randomly. NPH Insulin will be injected at the case segment subdermally and the control segment will be injected by normal saline in the same manner. Then transparent dressing will be used for covering the wounds. In the 7th, 14th and 21st-day postoperative periods some photos will be taken. The area of epithelialization in the scale of mm² will calculate by ImageJ software v1.52 and comparing between case and control groups will be done.

Participants/Inclusion and exclusion criteria

The population of the study will be consisted of patients who undergoing split-thickness skin graft surgery on the anterolateral region of thigh. Inclusion criteria: skin graft at least more than 10 cm length; age between 18 and 65 years. Exclusion criteria: aged under 18 years or above 65, history of diabetes, vascular diseases, smoking, and pregnancy.

Intervention groups

Subdermal injection will be done in twelve point of the case site with 2cc of NPH insulin (Exir®, Iran) with a concentration of 1 IU/ml. In control site, 2 cc of normal saline in 12 point will be injected subdermally.

Main outcome variables

The size of the epithelialized area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111118008122N2**

Registration date: **2019-06-24, 1398/04/03**

Registration timing: **retrospective**

Last update: **2019-06-24, 1398/04/03**

Update count: **0**

Registration date

2019-06-24, 1398/04/03

Registrant information

Name

Sohrab Moradi Bajestani

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 1317

Email address

dr.moradi@rocketmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-10, 1398/03/20

Expected recruitment end date

2019-06-15, 1398/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of local insulin injection on the healing process of split-thickness skin graft donor site in comparison to the placebo

Public title

The effect of local insulin injection on the wound healing process

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

STSG donor site at least more than 10 cm length and age between 18 and 65 year-old

Exclusion criteria:

Age below 18 years Age above 65 years Diabetes Malnutrition History of vascular diseases Smoking Pregnancy

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

15 patients will be enrolled in the current study and case and control group will be considered in one patient.

Regarding 9 cm width of split-thickness skin graft based on the width of the dermatome and >10 cm length of STSG, two 9×5cm segments in the proximal and distal part of the wound will be chosen as a case or control randomly and subdermal injection will be done with insulin or placebo.

Randomization (investigator's opinion)

Randomized

Randomization description

Using table of random numbers, case and control groups will be chosen (proximal or distal site of the wound).

Blinding (investigator's opinion)

Double blinded

Blinding description

This double-blind study will conduct in such a way that the patients and the assessing group will not know the site of drug injection and the choice of the injection site will be random.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Science, Enghelab St, Poursina Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-10-20, 1397/07/28

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.609

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

Skin Grafting

ICD-10 code

T86.82

ICD-10 code description

Complications of skin graft (allograft) (autograft)

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

evaluating epithelized area for assessing the wound site

Timepoint

At day 7, 14 and 21 after STSG

Method of measurement

ImageJ software

Secondary outcomes

empty

Intervention groups**1****Description**

In the case group, a single dose of NPH insulin (Exir, Iran) with the concentration of 1IU/ml and the dose of 2 ccs will be injected subdermally at 12 points of the wound. After the intervention, transparent dressing will be used for covering the wound. The wound site will be explored

at the 7th, 14th and 21st day of the postoperative period and some photos will be taken. in addition, measuring the blood glucose will be done in the pre and postoperative period in order to prevent insulin side effects such as hypoglycemia.

Category

Treatment - Drugs

2**Description**

Control group (Normal saline): It will be injected as a single dose of 2cc in 12 points subdermally like the insulin. After the intervention, transparent dressing will be used for covering the wound. The wound site will be explored at the 7th, 14th and 21st day of the postoperative period and some photos will be taken.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Razi Hospital

Full name of responsible person

Shahriar Haddady Abianeh

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Tehran Province, Tehran, District 12, Wahdat-e-Islami St.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shokoufeh Nikfar

Street address

Keshavarz Blvd., Ghods St. Tehran University of Medical Sciences

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Sohrab Moradi Bajestani

Position

Fellowship of Plastic Surgery

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Shahriar Haddady Abianeh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Sohrab Moradi Bajestani

Position

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All of the data can be shared

When the data will become available and for how long

After statistical analysis

To whom data/document is available

ethical committee

Under which criteria data/document could be used

in order to assess the data

From where data/document is obtainable

Dr. Sohrab Moradi

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

Sending an email

Comments