

# 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 mm<sup>2</sup> 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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1199663911

**Phone**

+98 21 5560 9951

**Email**

dr.smoradib@gmail.com

**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

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 81631

**Email**

rmo@tums.ac.ir

**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

**Street address**

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

**City**

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**Province**

Tehran

**Postal code**

1199663911

**Phone**

+98 912 377 0755

**Email**

dr.smoradib@gmail.com

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

Tehran University of Medical Sciences

**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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1199663911

**Phone**

+98 21 5560 9951

**Email**

h\_abianeh@yahoo.com

**Person responsible for updating data**

**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**

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**Email**

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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**