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

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

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**
+98 912 377 0755

**Email**
dr.smoradib@gmail.com

### 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**
Tehran

**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
Street address
Tehran Province, Tehran, District 12, Wahdat-e-Islami St.
City
Tehran
Province
Tehran
Postal code
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
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Tehran Province, Tehran, District 12, Wahdat-e-Islami St.
City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 912 377 0755
Email
dr.smoradib@gmail.com

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