Clinical Trial Protocol
Iranian Registry of Clinical Trials
19 Sep 2022

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
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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 outcomes
empty

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
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1
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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