

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of Stromal Vascular Fraction to induce vascular network formation in diabetic wounds

Protocol summary

Summary

The purpose of this study is to generate skin grafts containing their own intrinsic micro vascular plexus as a nutritional support for both, the dermal and the epidermal compartment by using the autologous SVF. The starting cell population was derived from the SVF (cells from the SVF can spontaneously develop a microvasculature) isolated from human adipose tissue, co-seeded with human keratinocyte and fibroblast cells and cultured on fibrin-collagen hydrogel scaffold. For this experiment we planned to study 10 patients assigned with diabetic wounds of less than 2mm² who are admitted in a Skin and stem cell research center. The Patients are randomized into two groups of case and control with 5 patients in each group. The Prepared hydrogel scaffold with and without cells processed from autologous fat and skin are applied to the diabetic wounds. The Wounds will become biopsied after fourth, 7th and 14th days and are evaluated for clinical and histopathological criteria of wound healing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110224834N1**

Registration date: **2015-11-29, 1394/09/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-29, 1394/09/08

Registrant information

Name

Mahsa Mollapour Sisakht

Name of organization / entity

Skin and Stemcell Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Skin and Stem Cell Research Center, Tehran University of Medical Sciences, Dr. Parvin Mansouri. Vice Chancellor for research of Kashan University of Medical Sciences, Dr. Gholamali Hamidi.

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Stromal Vascular Fraction to induce vascular network formation in diabetic wounds

Public title

Mesenchymal stem Cell application in diabetic wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: diabetic patients with less than 2 square millimeters wounds involvement. Exclusion criteria: (Actively) infected ulcer; Immune deficient patients; Patients with a known failed ipsilateral

revascularization procedure within 4 weeks prior to enrollment; Patients receiving systemic or injection of antiangiogenic drugs; Patients with poorly controlled diabetes mellitus.

Age

From **15 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Tehran University Ethics Committee in Research

Street address

No.21, 1st floor, Dameshgh St., Felestin St.,
Keshavarz blv.

City

Tehran

Postal code

Approval date

2015-10-20, 1394/07/28

Ethics committee reference number

IR.TUMS.REC.1394.989

Health conditions studied

1

Description of health condition studied

Diabetic wound

ICD-10 code

E10,E14

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

Vascularization in culture media (in Vitro)

Timepoint

Three weeks after transplantation

Method of measurement

Number of gap junction and pinocytotic vesicles of
counted by transmission electron microscopy analyses

2

Description

Sebometer

Timepoint

Fourth, 7th and 14th days after transplantation

Method of measurement

Biometry

3

Description

PHmeter

Timepoint

Fourth, 7th and 14th days after transplantation

Method of measurement

Biometry

4

Description

Pigmentation

Timepoint

Fourth, 7th and 14th days after transplantation

Method of measurement

Biometry

5

Description

Colorimeter

Timepoint

Fourth, 7th and 14th days after transplantation

Method of measurement

Biometry

6

Description

Skin Hydration

Timepoint

Fourth, 7th and 14th days after transplantation

Method of measurement

Biometry

7

Description

Cutometer

Timepoint

Fourth, 7th and 14th days after transplantation

Method of measurement

Biometry

8**Description**

Wound size

Timepoint

Fourth, 7th and 14th days after transplantation

Method of measurement

Count the squares (in centimeters) after placing the acetate sheet over a wound, measurements the size of the wound using a ruler

9**Description**

Graft take

Timepoint

Fourth, 7th and 14th days after transplantation

Method of measurement

Clinical judgment

10**Description**

Vascularization in In Vivo

Timepoint

Fourth, 7th and 14th days after transplantation

Method of measurement

Clinical judgment

11**Description**

Percentage of mature endothelial cells

Timepoint

Fourth, 7th and 14th days after transplantation

Method of measurement

Flowcytometry

Secondary outcomes**1****Description**

Wound infection

Timepoint

Fourth, 7th and 14th days after transplantation

Method of measurement

Appearance of wound

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

Intervention: Prepared scaffold with keratinocyte, fibroblast and SVF cells processed from autologous fat and skin, respectively, are applied in the diabetic wounds and wound healing would be monitored then after.

Category

Treatment - Surgery

2**Description**

Control: Prepared scaffold without cells in control group is applied in the diabetic wounds.

Category

Treatment - Surgery

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

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Full name of responsible person**Street address**

No. 4, Maryam deadend, South Kamranyeh, Tehran,
Iran.

City

Tehran

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

Vice Chancellor for research of Kashan University of
Medical Sciences,

Full name of responsible person

Dr. Gholamali Hamidi

Street address

Kashan University of Medical Sciences, Qotb Ravandi
Blvd, Kashan, Iran

City

Kashan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Kashan University of
Medical Sciences,

Proportion provided by this source**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***2****Sponsor**

Name of organization / entity

Vice Chancellor for research of Skin and Stem Cell
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Full name of responsible person

Dr.Parvin Mansouri

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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

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Research Center,

Proportion provided by this source**Public or private sector**

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Skin and Stemcell Research center, Tehran University
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Full name of responsible person

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PH.d candidate

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty