Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative study on effect of PRP-gel application and regular dressing on healing of diabetic wound

Protocol summary

Summary

The aim of this longitudinal, rehabitation single arm clinical trial was to evaluate the effectiveness of using autologous PRP gel for diabetic foot ulcer (DFU) treatment. Chronic DFU, considered as a wound in an extremity (mostly foot) of a known diabetic patient which has not decreased by 50% of the primary size in one month. 22 Patients with chronic DFUs after assessment of exclusion criteria : osteomyelitis, malignant arterial insufficiency, history of anti-proliferative medication or radiation in past 3 months, serum Hb<10 mg/dL, platelet count<103/µL and history of growth factor therapy within last 2 weeks and obtaining inform consent were enrolled in the study. In this clinical trial, PRP gel therapy (2ml/cm2 of ulcers) was performed and consequently , size of ulcer was measured before dressing weekly until the healing time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015123018842N10**
Registration date: **2016-02-07, 1394/11/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-07, 1394/11/18

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Hematology, Oncology and Stem Cell Transplantation Research Center

Expected recruitment start date

2013-04-20, 1392/01/31

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study on effect of PRP-gel application and regular dressing on healing of diabetic wound

Public title

Efficacy of platelet gel on diabetic foot ulcer

Purpose

Supportive

Inclusion/Exclusion criteria

Patients with chronic DFUs were enrolled in the study. Chronic DFU, considered as a wound in an extremity (mostly foot) of a known diabetic patient which has not decreased by 50% of the primary size in one month (Inclusion criteria). No other limitations such as age, sex, fasting blood sugar (FBS) or hemoglobin A1C (Hb A1C) levels were applied.Exclusion criteria included osteomyelitis, malignant arterial insufficiency, exposed bone in an ulcer, antibiotic resistance DFU, wounds with Charcot deformity, history of anti-proliferative

medication or radiation in past 3 months, serum Hb<10 mg/dL, platelet count<103/µL and history of growth factor therapy within last 2 weeks.

Age
From **35 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hematology, Oncology and Stem Cell Transplantation Research Center

Street address
North Kargar St., Shariat Hospital

City
Tehran

Postal code
1411713135

Approval date
2015-12-24, 1394/10/03

Ethics committee reference number
ir.tums.horcsct.rec.1394.103.3

Health conditions studied

1

Description of health condition studied
Insulin-dependent diabetes mellitus

ICD-10 code
E10

ICD-10 code description
Insulin-dependent diabetes mellitus

2

Description of health condition studied
Non-insulin-dependent diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

3

Description of health condition studied
Other specified diabetes mellitus

ICD-10 code
E13

ICD-10 code description
Other specified diabetes mellitus

4

Description of health condition studied
Unspecified diabetes mellitus

ICD-10 code
E14

ICD-10 code description
Unspecified diabetes mellitus

Primary outcomes

1

Description
Ulcer size

Timepoint
weekly up to full healing

Method of measurement
Ruler

Secondary outcomes

1

Description
Efficacy of platelet gel on prevention of foot amputation

Timepoint
mounthly after strat treatment

Method of measurement
visit by surgeon

Intervention groups

1

Description
Dressing of ulcer with Autologous platelet rich plasma gel which is activated by cacl2 (2 ml/cm2) weekly up to full healing

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Vascular Surgery of Shariati Hospital
Full name of responsible person
Behnam Molavi
Street address
North Kargar St., Shariati Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hematology, Oncology and Stem Cell Transplantation Reseach Center
Full name of responsible person
Mojtaba Ramezani
Street address
North Kargar St., Shariati Hospital
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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
Hematology, Oncology and Stem Cell Transplantation Reseach Center
Proportion provided by this source
100
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

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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