

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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, rehabilitation 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/ μ L 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

Name

Leyla Sharifi Aliabadi

Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation, Tehran University of Medic

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Iran (Islamic Republic of)

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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

monthly 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

Contact

Name of organization / entity

Hematology, Oncology and Stem Cell Transplantation
Resaerch Center

Full name of responsible person

Saeed Mohammadi

Position

PhD

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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