Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

The effect of combination therapy of vitamin E and C supplements plus Platelet-Rich Plasma-Fibrin Glue on biochemical factors, oxidative stress markers and wound healing rate in diabetic patients

Protocol summary

Study aim

The aim of this study was to increase the chance of diabetic ulcer repair by reducing oxidative stress caused by diabetes by taking vitamin E and C supplements along with the use of Platelet-Rich Plasma-Fibrin Glue as an effective treatment for wound healing.

Design

A randomized, single blind clinical trial, based on patients with diabetic ulcers, which has two parallel groups.

Settings and conduct

24 patients with diabetic wounds among diabetic patients referring to Imam Reza Hospital in Mashhad who have been diagnosed to have wounds with grade 2 to 4 wagners classification by a vascular surgeon will be divided into intervention group, includes patients receiving PRP-Fibrin-Glue treatment plus vitamin supplements (E (200 IU / 2day) and (C (250 mg / 2day) or controls group which will be treated with PRP-Fibrin-Glue alone for 8 weeks.

Participants/Inclusion and exclusion criteria

Patients with grade 2- 4 diabetic wounds based on Wagner's classification, having wounds on the legs and extremities, no smoking, alcohol or drug addiction, non-use of drugs that may interfere with wound healing, such as corticosteroids, immunosuppressive agents, and cytotoxic agents, not having an illness that may cause problems in wound healing, such as cancers, vasculitis, age between 40 and 75 years, HbA1c over 7 within last 3 months, at least 4 weeks have elapsed since the wounds occurred.

Intervention groups

Intervention group consist of Patients with diabetic ulcer treated with PRP-Fibrin-Glue plus vitamin supplements (E (200 IU / 2day) and C (250 mg / 2day)) for 8 weeks. Control group consist of Patients with diabetic ulcer treated with PRP-Fibrin-Glue for 8 weeks.

Main outcome variables

The amount of wound healing and the area of the wound will be measured at the beginning of the study, and then every week for 2 months.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190526043711N1**
Registration date: **2019-09-02, 1398/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-02, 1398/06/11**
Update count: **0**

Registration date

2019-09-02, 1398/06/11

Registrant information

Name

Amir Yarahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 8574

Email address

yarahmadia961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combination therapy of vitamin E and C supplements plus Platelet-Rich Plasma-Fibrin Glue on biochemical factors, oxidative stress markers and wound healing rate in diabetic patients

Public title

The effect of combination therapy of vitamin E and C supplements plus Platelet-Rich Plasma-Fibrin Glue on biochemical factors, oxidative stress markers and wound healing rate in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with grade 2- 4 diabetic wounds based on Wagner's classification Having wounds on the legs and extremities No smoking, alcohol or drug addiction Non-use of drugs that may interfere with wound healing, such as corticosteroids, immunosuppressive agents, and cytotoxic agents. Not having an illness that may cause problems in wound healing, such as cancers, vasculitis Age between 40 and 75 years HbA1c over 7 within last 3 months At least 4 weeks have elapsed since the wounds occurred

Exclusion criteria:

The presence of ulcer with active infection and the need for intravenous antibiotics Gangrene which needs amputation Lack of patient referral to the center for tracking and changing dressings in more than two occasions Previous consumption of vitamin E and C supplements Patients with renal and hepatic failure and heart failure Patients with advanced diabetic retinopathy Pregnancy or breastfeeding HbA1c more than 11 Occurrence of special medical conditions

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyst will not be aware of the allocation of individuals in the groups analyzed and reviewed

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Iman Reza Hospital, Daneshgah Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9181111111

Approval date

2019-05-25, 1398/03/04

Ethics committee reference number

IR.MUMS.REC.1398.125

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

E10-E14

ICD-10 code description

With peripheral circulatory complications

Primary outcomes

1

Description

Healing rate of the ulcer

Timepoint

At the beginning of the study, and then every week for 2 months.

Method of measurement

Examination by a vascular surgery physician and documentation

2

Description

The size of the ulcer

Timepoint

At the beginning of the study, and then every week for 2 months.

Method of measurement

Measuring by ruler and documentation

Secondary outcomes

1

Description
Serum hs-CRP
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

2

Description
Fasting blood sugar
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

3

Description
Serum insulin
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

4

Description
Serum Triglyceride
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

5

Description
Serum Cholesterol
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

6

Description
Serum HDL
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

7

Description
Serum LDL
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

8

Description
Serum Urea
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

9

Description
Serum Creatinine
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

10

Description
Serum total bilirubin
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

11

Description
HbA1c
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

12

Description
Serum Uric acid
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

13

Description
Serum Malondialdehyde
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

14

Description
Serum reduced Glutathione
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

15

Description
Total Antioxidant Capacity
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

16

Description
Serum levels of vitamins E
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

17

Description
Serum levels of vitamins C
Timepoint
At the beginning of the study and the end of the trial
Method of measurement
In a quantitative laboratory method

Intervention groups

1

Description
Control group: Patients with diabetic ulcer treated with PRP-Fibrin-Glue for 8 weeks.
Category
Treatment - Other

2

Description
Intervention group: Patients with diabetic ulcer treated with PRP-Fibrin-Glue plus vitamin supplements (E (200 IU / 2day) and C (250 mg / 2day)) for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Daryoush Hamidi Alamdari
Street address
Iman Reza Hospital, Daneshgah Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3882 8574
Email
hamidiad@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Mashhad University of Medical Sciences, Daneshgah Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
91388-13944
Phone
+98 51 3882 3255
Email
tafaghodiM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Daryoush Hamidi Alamdari
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Iman Reza Hospital, Daneshgah Ave
City

Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3882 8574
Email
hamidiad@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Daryoush Hamidi Alamdari
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Iman Reza Hospital, Daneshgah Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3882 8574
Email
hamidiad@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Amir Yarahmadi
Position
Ph.D Student
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Iman Reza Hospital, Daneshgah Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9189511111
Phone
+98 51 3882 8574
Email
yarahmadiA961@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data related to the project after unidentifiable of people will be shared.
When the data will become available and for how long
Access to data are allowed 6 months after the publication of results.
To whom data/document is available
Our data will be available for university staffs and academic institutions.
Under which criteria data/document could be used
All types of analysis for data are allowed by authorized researchers.
From where data/document is obtainable
yarahmadiA961@mums.ac.ir
What processes are involved for a request to access data/document
Accept permission from the project implementer for the applicant
Comments