

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of platelet dressing on the healing of diabetic foot ulcers compared with routine dressing in patients with diabetic foot ulcers Shahid Beheshti Hospital

#### Protocol summary

##### Summary

(1) Objectives, The overall aims are Examines the impact of platelet dressing on the healing of diabetic foot ulcers compared with routine dressing. (2) Design, The study design is a randomized clinical trial. (3) Setting and conduct, after referring patients with diabetic foot ulcers and checked by an infectious, qualified Patients for the study are selected and divided into two groups of case and control. For the treatment group, after the preparation of platelet from the patients blood, a platelet dressing will be done with 5 cc platelet rich plasma. This dressing will be removed from after three days followed by a simple normal saline dressing just the same as control group. Pictures will be taken on days 1, 7, 14 and 21 and finally the weight of the wound is calculated using software. A metal measure will be used to evaluate the depth of the wound and results will be monitored in the checklist. For the control group, dressing will also be done every day with normal saline. Finally Changes in the wounds as well as their depth and time of improvement will be calculated and compared (4). Inclusion criteria involves those with foot ulcer in the first or second Wagner phase, patients with equal number of platelet or more than 100,000, patient with HG at least 10, patients without clotting problems, and patients without immune suppressor medicine.(5) Interferences include wound debridement, blood sampling, dressing the wound with platelet rich gauze and dressing change(6). Variables are as platelet dressing (as independent) and wound depth and time of wound healing will be the dependent variables

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014060415574N3**

Registration date: **2014-11-19, 1393/08/28**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-11-19, 1393/08/28

##### Registrant information

###### Name

Mohammad Afshar

###### Name of organization / entity

Medical kashan

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5557 0278

###### Email address

mohammad.afshar@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Project costs will be paid by the Vice chancellor for research, kashan University of Medical Sciences

##### Expected recruitment start date

2014-07-23, 1393/05/01

##### Expected recruitment end date

2015-07-23, 1394/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of platelet dressing on the healing of diabetic foot

ulcers compared with routine dressing in patients with diabetic foot ulcers Shahid Beheshti Hospital

#### **Public title**

Effect of platelet dressing on wound healing in diabetic foot

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: diabetic patients with foot ulcers who entered is stage 1 or 2 foot ulcers: Patients with a platelet count equal to or greater than 100,000: Patients who have a minimum of 10 HB: Not taking medications that suppress the immune system; Patients who have no known clotting problems. exclusion criteria: Signs of sepsis in patients

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

No information

#### **Sample size**

Target sample size: 60

#### **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**

Ethics Committee for Kashan University of Medical Sciences

###### **Street address**

5th of Qotb- e Ravandi Blvd, Kasha

###### **City**

Kashan

###### **Postal code**

87135/1416

##### **Approval date**

2014-07-23, 1393/05/01

##### **Ethics committee reference number**

9321

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Diabetic foot ulcers

##### **ICD-10 code**

E10, E11,

##### **ICD-10 code description**

With peripheral circulatory complications

### **Primary outcomes**

#### **1**

##### **Description**

Platelet dressing

##### **Timepoint**

Days 1, 7, 14 and 21

##### **Method of measurement**

by checklist

### **Secondary outcomes**

#### **1**

##### **Description**

Wound area

##### **Timepoint**

Days 1, 7, 14 and 21

##### **Method of measurement**

Calculate the area of the wound, through the Photo And its analysis software and recorded by the Checklist of wound

#### **2**

##### **Description**

Wound healing

##### **Timepoint**

Days 1, 7, 14 and 21

##### **Method of measurement**

by the Checklist

#### **3**

##### **Description**

Depth of wound

##### **Timepoint**

Days 1, 7, 14 and 21

##### **Method of measurement**

Measure the depth by the Measurements and record in the Checklist

#### **4**

##### **Description**

During wound healing

##### **Timepoint**

Days 1, 7, 14 and 21

##### **Method of measurement**

by the Checklist

## Intervention groups

### 1

#### Description

Intervention group: in intervention group Samples are selected among the diabetic patients with foot wound diagnosed by the infection disease specialist at Shahid Beheshti hospital in the first or second Wagner scale. Patients will be examined for the eligibility for using platelet treatment. Patient will be divided in two groups (treatment- control) and treatment group will be informed regarding to their treatment procedures. At the first phase, demographic data will be gathered about the wound and results of blood tests in two separated checklists .debridement will be done for each case if needed. For the treatment group, after disinfection of the cubital fossa, 50 cc of blood will be drawn gathered in falcon sterile tubes. Samples are centrifuged for 200r/m for 20 minutes. Then the PRP will be gathered and transferred to another tube. For all samples, platelets are calculated and 100,000 concentrations will be prepared. Those with lower platelet count will be excluded. After preparing the PRP, 5 cc of it will be used for wound dressing using a 5 cc syringe we pour the PRP on the sterile gauze ant put it on the wound covering with sterile gauze. This PRP dressing will remain for 3 days on the wound. After that, other wounds will be dressed by normal saline and wounds will be evaluated on days 7, 14 and 21 by a digital camera that gets pictures from the wounds from 30 cm distance. The weight of the wounds will be assessed by software and their depth will be evaluated using a metal measure. Finally all registered data will be compared in treatment and control groups.

#### Category

Treatment - Other

### 2

#### Description

control groups: First, patients with diabetic foot ulcers who are stage 1 or 2 according to Wagner have been examined by a specialist in infectious And qualify for inclusion in the need for surgical debridement for their advice is requested.After debridement, the wound was irrigated with normal saline and sterile gauze dressing is routine. Dressing change on a daily basis will be the control group.Dressing change on a daily basis will be the control group.In this group, such as group therapy and depth of the wound area on days 1, 7, 14 and 21 measured And changes in the size and depth of the wound area in the two groups were compared with each other.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Beheshti hospital, Kashan

#### Full name of responsible person

Mohammad Afshar

#### Street address

Beheshti hospital, 5th of Qotb –e Ravandi Blvd,  
Kashan

#### City

Kashan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Kashan University of  
Medical Sciences

##### Full name of responsible person

Gholamali Hamidi

##### Street address

5th of Qotb –e Ravandi Blvd, Kashan

##### City

Kashan

#### Grant name

#### Grant code / Reference number

9321

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor for research, Kashan University of  
Medical Sciences

#### 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

Kashan University of Medical Sciences

##### Full name of responsible person

Mohammad Afshar

##### Position

Masters/Lecturer

##### Other areas of specialty/work

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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## Person responsible for updating data

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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*