

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 2026

### Comparison of the Effect of PRP (Platelet Rich Plasma) Injection Plus Standard Treatment and Just Standard Treatment in Healing of Diabetic Foot Ulcer in Diabetic Patients

#### Protocol summary

##### Summary

**Objectives:** Diabetes is a well-known metabolic disorder which can raise the possibility of infection or ulcers' healing delay. Control and protection of diabetic foot ulcers is very important. The aim of this study is to compare the effect of PRP (Platelet Rich Plasma) with standard treatment (cleaning with normal saline) in healing of diabetic foot in diabetic patients. **Design:** In this trial, 50 diabetic (type 1 or 2) patients with diabetic foot ulcers aged 40-70 years old will be randomly entered into one of the treatment groups and their demographic information and ulcers' sizes will be recorded. **Setting and conduct:** The patients in the first group will receive daily ulcer cleaning with normal saline plus weekly intra-ulcer injection of PRP and the patients of the second group will receive just daily cleaning with normal saline. A surgeon will assess the healing rate and the sizes of ulcers at the beginning of the treatment and then weekly. **Major Inclusion and Exclusion criteria:** The presence of at least 4 weeks of diabetic foot ulcer in patients with diabetes type 1 or 2 and being an uncomplicated ulcer. **Intervention:** Daily ulcer cleaning with normal saline plus weekly intra-ulcer PRP injection or just daily ulcer cleaning with normal saline. **Main outcome measures (variables):** The sizes and rate of ulcers' healing will be recorded during the treatment and finally the result of the groups will be compared with each other.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015021519037N5**

Registration date: **2015-02-24, 1393/12/05**

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

Last update:

Update count: **0**

##### Registration date

2015-02-24, 1393/12/05

##### Registrant information

###### Name

Mahdieh Yousef-Zanjani

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3333 6004

###### Email address

yusefi.mahdieh@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Investigator

##### Expected recruitment start date

2014-09-06, 1393/06/15

##### Expected recruitment end date

2015-03-06, 1393/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effect of PRP (Platelet Rich Plasma) Injection Plus Standard Treatment and Just Standard Treatment in Healing of Diabetic Foot Ulcer in Diabetic Patients

##### Public title

Assessing the Effect of PRP (Platelet Rich Plasma)  
Injection in Healing of Diabetic Foot Ulcer

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Diabetic foot ulcer in patients with diabetes type 1 or 2 for at least 4 weeks. Exclusion criteria: Infected ulcers, ulcers with Charcot deformities, ulcers with bone involvement, ulcers with the size less than 0.5 or more than 20 cm, pregnant or nursing patients.

## Age

From **40 years** old to **70 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

The patients will be randomly divided into the treatment groups by usage of colored carts.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

##### Street address

Shahid-Bahonar Boulevard

##### City

Qazvin

##### Postal code

#### Approval date

2014-06-12, 1393/03/22

#### Ethics committee reference number

28.20.8858

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes Mellitus

#### ICD-10 code

E10-E14

#### ICD-10 code description

Diabetes Mellitus

### 2

#### Description of health condition studied

Diabetes Mellitus with Peripheral Circulatory Complications

#### ICD-10 code

I79.2\*

#### ICD-10 code description

Peripheral Angiopathy in Diseases Classified Elsewhere (Diabetic Peripheral Angiopathy / Ulcer)

## Primary outcomes

### 1

#### Description

Healing rate of the ulcer

#### Timepoint

At the beginning of the treatment, 1, 2, 3 and 4 weeks after the beginning of the treatment

#### Method of measurement

Assessing by one surgeon and documentation

### 2

#### Description

The size of the ulcer

#### Timepoint

At the beginning of the treatment, 1, 2, 3 and 4 weeks after the beginning of the treatment

#### Method of measurement

Measuring by ruler and documentation

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First intervention group (Trial group): Daily cleaning of the ulcer with 1 liter normal saline as the standard treatment (normal saline solution 9mg/ml from Daroupakhsh drug manufacturing company, Tehran, Iran, registered No. 1228057458) with weekly intra-ulcer injection of PRP (2 ml autologous centrifuged platelet-rich plasma) up to 4 doses

#### Category

Treatment - Drugs

## 2

### Description

Second intervention group (Controll group): Just daily cleaning of the ulcer with 1 liter normal saline as the standard treatment (normal saline solution 9mg/ml from Daroupakhsh drug manufacturing company, Tehran, Iran, registered No. 1228057458)

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Velayat General Hospital

##### Full name of responsible person

Dr. Heidar Afshar

##### Street address

Taavon Square

##### City

Qazvin

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Investigator

##### Full name of responsible person

Dr. Heidar Afshar

##### Street address

Velayat General Hospital, Taavon Square

##### City

Qazvin

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Investigator

#### 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

Qazvin University of Medical Sciences

#### Full name of responsible person

Dr. Hossein Parsa

#### Position

Vascular Surgeon, Professor

#### Other areas of specialty/work

#### Street address

Velayat General Hospital, Taavon Square

#### City

Qazvin

#### Postal code

#### Phone

+98 28 3379 0620

#### Fax

#### Email

hoparsaar2004@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Velayat Hospital

#### Full name of responsible person

Dr. Heidar Afshar

#### Position

General Surgery Resident

#### Other areas of specialty/work

#### Street address

Taavon Square

#### City

Qazvin

#### Postal code

#### Phone

+98 28 3379 0620

#### Fax

#### Email

yusefi.mahdieh@yahoo.com

#### Web page address

## Person responsible for updating data

### Contact

## 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