# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## To evaluate the efficacy and safety of applied autologous circulating fibrocytes in the treatment of non-healing diabetic foot ulcer; a pilot study

## Protocol summary

**Summary**

The aim of this study is to evaluate a new cellular therapy for the treatment of chronic non-healing diabetic wounds. 20 patients affected with the type II DM, with the wet wounds, about 2-6 cm2, resistant to treatment despite of the comprehensive treatments for at least 6 weeks, wounds in the grade II, III and IV based on the Wagner classification method, without osteomyelitis, cellulits, or any kind of the local and systemic infection and no other underlying disease rather than DM (as autoimmune diseases) will be selected. 10 patients in the test group will receive once cellular graft with dressing (cell suspension). The dressings will be changed every 7 days up to the 8th week or the complete wound healing. The other 10 patients in the control group will receive dressing without cellular graft. Wound healing will be assessed by the evaluation of the changes of the wound dimensions and need to amputation.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138812133487N1**
Registration date: **2010-04-03, 1389/01/14**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2010-04-03, 1389/01/14

**Registrant information**

**Name**

Mohaddeseh Behjati

**Name of organization / entity**

Isfahan University of Medical Sciences

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**Recruitment status**

**Recruitment complete**

**Funding source**

Isfahan Univeristy of Medical Sciences, Royan Research Institiute

**Expected recruitment start date**

2010-05-01, 1389/02/11

**Expected recruitment end date**

2011-12-01, 1390/09/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

To evaluate the efficacy and safety of applied autologous circulating fibrocytes in the treatment of non-healing diabetic foot ulcer; a pilot study

**Public title**

To evaluate new cellular therapy for non-healing diabetic foot ulcer

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: both males and females, age 40-70 years old, with wounds area ranging from 2 to 6 cm2, (exposed bones may also be included if other criteria are filled), healing refractory despite comprehensive treatment for at least 6 weeks and Grade II, III and IV of

Wagner's classification system (wound will be debrided), Wounds in the Gangrene stage are included if they are wet, but suppurative wounds may be enrolled after complete treatment of the infection. Mostly wounds with the cavity formation will be preferred to enrolled, as in the cases after debridement with a remained cavity unfilled with healed tissues, compliant, alert enough to understand the process of the research project which are high risk for amputation and are not indicated for vascular surgery or are unable to endure surgery are considered to be included. Exclusion criteria: Non-healing wounds with clinically or laboratory (ESR, CBC, CRP) diagnosed osteomyelitis, cellulitis or any kind of infection before infection control, Dry gangrene which makes no problem for the patient, patients with overt malignancy, chronic kidney disease over stage III, uncontrolled hyperglycemia (HbA1C> 9%) and other underlying disease other than DM (based on their files and caring physician information), other causes of non-inclusion are pregnancy, lactation, Poor hygiene, Consumption of special drugs with the effect on wound healing. patients with mental or psychological disorders and cases who are unable to understand or perceive the process of getting informed consent completely.

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

**Gender**
Both

**Phase**
1

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **20**

**Randomization (investigator's opinion)**
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Isfahan University of Medical Sciences

**Street address**
Ethics Committee, Vice-chancellory for research, Isfahan University of Medical Sciences

**City**
Isfahan

**Postal code**
81745-319

**Approval date**
empty

**Ethics committee reference number**
188078

## Health conditions studied

### 1

**Description of health condition studied**
Non-healing diabetic foot ulcer

**ICD-10 code**
E11.5

**ICD-10 code description**
Non-insulin-dependent diabetes mellitus With peripheral circulatory complications. Diabetic ulcer

## Primary outcomes

### 1

**Description**
wound area

**Timepoint**
every 7 days up to 8th week then bi-weekly up to 6 months

**Method of measurement**
Paper ruler, digital camera, lab data and clinical observation

### 2

**Description**
patient satisfaction scores

**Timepoint**
at 2-6-9-12 months

**Method of measurement**
patient satisfaction scores based on the VAS scoring system

### 3

**Description**
occurrence of unexplained fever, weight loss

**Timepoint**
every 7 days up to 8th week then bi-weekly up to 6 months

**Method of measurement**
clinical observation

### 4

**Description**
wound healing process

**Timepoint**
every 7 days up to 8th week then bi-weekly up to 6 months

**Method of measurement**
Paper ruler, digital camera, lab data and clinical

observation

**5**

**Description**
local complications
**Timepoint**
every 7 days up to 8th week then bi-weekly up to 6 months
**Method of measurement**
clinical observation

**6**

**Description**
clinical or laboratory abnormalities
**Timepoint**
3, 6, 12 and 19th months
**Method of measurement**
lab data and clinical observation

**7**

**Description**
Wound healing time
**Timepoint**
every 7 days up to 8th week then bi-weekly up to 6 months
**Method of measurement**
Paper ruler, digital camera, lab data and clinical observation

## Secondary outcomes

**1**

**Description**
Need to amputation
**Timepoint**
3, 6, 12 and 19th months
**Method of measurement**
Clinical observation, lab data

**2**

**Description**
abnormal renal or hepatic function tests
**Timepoint**
3, 6, 12 and 19th months
**Method of measurement**
lab data

**3**

**Description**
mortality
**Timepoint**
from the begining of the study up to the 19th months
**Method of measurement**
Death occurrence

## Intervention groups

**1**

**Description**
cell graft plus dressing (cell suspension) applied once over the wound, but the dressing will be changed weekly to the time of wound healing or up to the 8 week
**Category**
Other

**2**

**Description**
Control group receive dressing without cellular graft, and the dressing will be changed every 7 days up to the 8 week or the complete wound healing.
**Category**
Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Amin Hospital-Isfahan University of Medical Sciences
**Full name of responsible person**
Dr. Hashemi Fesharaki
**Street address**
Amin Hospital, Shohada square, Ebnesina St
**City**
Isfahan

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Isfahan University of Medical Sciences
**Full name of responsible person**
Peymain Adibi
**Street address**
Isfahan University of Medical Sciences
**City**
Isfahan
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Isfahan University of Medical Sciences
**Proportion provided by this source**
**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*

**2**

**Sponsor**
**Name of organization / entity**
Royan Research Center
**Full name of responsible person**
Mohammad Hossein Nasr Esfahani
**Street address**
Royan center, Aban Alley, Mehr St, Isfahan
**City**
Isfahan
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Royan Research Center
**Proportion provided by this source**
**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**
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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*