Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
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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

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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