# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Phase II controlled clinical trial to evaluate safety and efficacy of Angipars in patients with diabetic foot ulcer in Syria

## Protocol summary

**Summary**

This is a phase II clinical trial in which thirty patients known to have diabetic foot ulcer seeking medical attention in pre-specified centers in Syria will be enrolled in the study. All the patients will be evaluated in terms of meeting a set of inclusion/exclusion criteria (Presence of diabetic foot ulcer for a minimum duration of 1 months, Wound size more than 2 cm squared, etc) and sign a written informed consent prior to recruitment. Patients will receive an oral-topical combination of ANGIPARS twice a day for 8 weeks plus standard wound care. The patients in control group will recieve only standard wound care. Primary outcome measure of this study would be wound size measured in mm2 by multiplying the longest and the shortest wound diameters in mm. Complete wound closure, Ankle Brachial Pressure Index, patient's quality of life, patient and physician's global impression will also be assessed as secondary outcome measures.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201102204272N2**
Registration date: **2011-02-20, 1389/12/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2011-02-20, 1389/12/01

**Registrant information**

**Name**

Dr Faten Al akkad

**Name of organization / entity**

Ministry of Health, Syria

**Country**

Syrian Arab Republic

**Phone**

00963112758133

**Email address**

dqc.dir@moh.gov.sy

**Recruitment status**

**Recruitment complete**

**Funding source**

Pars Roos Biotechnology Co.

**Expected recruitment start date**

2010-11-01, 1389/08/10

**Expected recruitment end date**

2011-06-01, 1390/03/11

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Phase II controlled clinical trial to evaluate safety and efficacy of Angipars in patients with diabetic foot ulcer in Syria

**Public title**

Phase II clinical trial of Angipars in patients with diabetic foot ulcer in Syria

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Diagnosis of Diabetes Mellitus (Type 1 or 2) defined by American Diabetes Association criteria for at least 3 years; Presence of diabetic foot ulcer for a minimum duration of 1 months due to various reasons such as peripheral neuropathy, foot deformity, trauma or inappropriate shoes' limitation of activity, uncontrolled blood glucose, long term diabetes mellitus, etc.; Wound size more than 2 cm squared; Age more than 18 and less

than 75; Exclusion criteria: Presence of acute infection of the ulcer with or without pus drainage or erythema of the ulcer margins of 3 cm width; Presence of wound with visible bone or signs suggestive of acute osteomyelitis; Presence of severe cardiac condition with functional class of 3 or higher or under treatment; Presence of signs and symptoms suggestive of severe and chronic ischemia with absence of peripheral pulses (absence of peripheral pulse alone is not an exclusion criteria); Any concurrent diseases or conditions which delay wound healing (cancer, vasculitis, ect.); Drug and alcohol abuse; Presence of chronic renal failure on hemodialysis or peritoneal dialysis; Treatment with corticosteroids, immune suppressants, radiotherapy or chemotherapy; Any known drug hypersensitivity; Inability or refusal to sign the informed consent; Receiving any investigational drug within 30 days prior to screening; Pregnancy or intention of becoming pregnant during the study period.

**Age**
From **18 years** old to **75 years** old

**Gender**
Both

**Phase**
2-3

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

**Sample size**
Target sample size: **30**

**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**
Syria Ministry of Health Ethics committee

**Street address**
Ministry of Health, Damascus, Syria

**City**
Damascus

**Postal code**

**Approval date**
2010-05-20, 1389/02/30

**Ethics committee reference number**
6504

## Health conditions studied

### 1

**Description of health condition studied**
Diabetic foot ulcer

**ICD-10 code**
I79.2

**ICD-10 code description**
Peripheral angiopathy in diseases classified elsewhere. Diabetic peripheral angiopathy

## Primary outcomes

### 1

**Description**
Wound size

**Timepoint**
Begining, Weeks 2, 6, 8, 12 ,16 and 20

**Method of measurement**
Measurment

## Secondary outcomes

### 1

**Description**
Wound closure

**Timepoint**
Begining, Weeks 2, 6, 8, 12 ,16 and 20

**Method of measurement**
examination

### 2

**Description**
Ankle-Brachial Pressure Index

**Timepoint**
Begining, Weeks 2, 6, 8, 12 ,16 and 20

**Method of measurement**
Examination

### 3

**Description**
Quality of life

**Timepoint**
Begining, Weeks 2, 6, 8, 12 ,16 and 20

**Method of measurement**
Filling the questionaire

### 4

**Description**
Patient Global Impression of Change

**Timepoint**
Weeks 2, 6, 8, 12 ,16 and 20

**Method of measurement**
Interview

**5**

**Description**
Physician Global Impression of Change
**Timepoint**
Weeks 2, 6, 8, 12 ,16 and 20
**Method of measurement**
Physicians evaluation

## Intervention groups

**1**

**Description**
Intervention group: In addition to standard daily wound care, each patient will receive ANGIPARSTM one capsule, 120mg bid for 8 weeks and topical cream bid. The cream should be rubbed around the wound and a thin layer on the surface of the wound.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: In control group patients will recieve only standard wound care
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Al Mujtahid hospital
**Full name of responsible person**
Dr. Faten Alakkad
**Street address**
Al Mujtahid hospital, Al Midan, Damascus, Syria
**City**
Damascus

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Pars Roos Biotechnology Co.
**Full name of responsible person**
Dr. Koorosh Kamali
**Street address**
No 568, 13 th Alley, Hormozan St., Shahrak-e- gharb
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Pars Roos Biotechnology Co.
**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**
Clinical trial Department
**Full name of responsible person**
Dr. Faten Alakkad
**Position**
Head of Department
**Other areas of specialty/work**
**Street address**
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00963112758133
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faten.alakkad@hotmail.com
**Web page address**

## Person responsible for scientific inquiries

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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*