

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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 receive only standard wound care. Primary outcome measure of this study would be wound size measured in mm<sup>2</sup> 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**

Beginning, Weeks 2, 6, 8, 12, 16 and 20

**Method of measurement**

Measurement

**Secondary outcomes****1****Description**

Wound closure

**Timepoint**

Beginning, Weeks 2, 6, 8, 12, 16 and 20

**Method of measurement**

examination

**2****Description**

Ankle-Brachial Pressure Index

**Timepoint**

Beginning, Weeks 2, 6, 8, 12, 16 and 20

**Method of measurement**

Examination

**3****Description**

Quality of life

**Timepoint**

Beginning, Weeks 2, 6, 8, 12, 16 and 20

**Method of measurement**

Filling the questionnaire

**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 receive 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

Clinical trial department, Al Mujtahid hospital, Al Midan, Damascus, Syria

##### City

Damascus

##### Province

Damascus

##### Postal code

##### Phone

00963112758133

##### Fax

##### Email

faten.alakkad@hotmail.com

##### Web page address

## Person responsible for scientific 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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## Person responsible for updating data

### 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**

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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*