

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 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

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

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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