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
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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