A phase II study of ARA 290 as therapeutic strategy in no-option critical limb ischemia patients.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28106

Source
Nationaal Trial Register

Health condition

Critical limb ischemia

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

1. Safety and tolerability parameters;

2. General safety measurements;

3. 12-lead ECG (only base line and visits on day 5 and 26);

4. Hematology;

5. Blood Biochemistry;

6. Adverse Event monitoring;

7. Pain Scores (VAS + Brief Pain Inventory);

8. Allodynia and Hyperalgesia Testing;

9. Autonomic nervous system measurement (only baseline and day 5);

10. Analgesics use (diary);

11. Wound healing (calibrated photos);

12. Circulating inflammatory markers;

13. Insulin sensitivity (fasting HOMA);

14. Quality of life (RAND-36) (only base line and day 26).

Secondary outcome

N/A

Study description

Background summary

N/A

Study objective

The objective of this proof-of-concept study is to test in no-option CLI patients whether ARA 290 (a) reduces limb pain, (b) reduces signs of local and systemic inflammation, and (c) promotes wound healing.

Study design

Day 1, 3, 5, 8, 10, 12, 15, 17, 19, 22, 24 and 26.

Intervention

ARA 290 is an 11-amino acid, linear peptide that is being developed as a tissue protective peptide. ARA 290 is manufactured by standard F-moc solid phase peptide synthesis, purified by HPLC and ion-exchange chromatography, and stored as a lyophilized powder. ARA-290 will be administered 3 times a week for 4 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Critical limb ischemia;

2. No option for conventional revascularization;

3. Written informed consent;

4. Expected life expectancy > 1 year.

Exclusion criteria

1. Poorly regulated diabetic disease (HbA1c >10%);

2. Clinically relevant abnormal history of physical and mental health other than conditions related to CLI, as determined by medical history taking (as judged by the investigator);

3. Clinically relevant abnormal laboratory results, ECG, vital signs, or physical findings other than conditions related to CLI (as judged by the investigator);

4. Subject has a history of severe allergies, or has had an anaphylactic reaction or significant intolerability to prescription or non-prescription drugs or food;

5. Participation in an investigational drug trial in the 3 months prior to administration of the initial dose of study drug or more than 4 times per year;

6. Use of erythropoietin, systemic corticosteroids (e.g. prednisone etc.) and other immune modulatory drugs;

7. Inability to follow the protocol and to comply with the follow up requirements;

8. Any other condition that in the opinion of the investigator would complicate or compromise the study, or the well being of the subject.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	12-01-2011
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion
Date: 10-01-2011
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2294
NTR-old	NTR2685
Other	METC LUMC / ABR : P10.85 / NL31947.058.10 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A