# 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

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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%);
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- 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 wordt niet meer aangevraagd.

# **Study results**

## **Summary results**

N/A