# 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);

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- 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

#### Public

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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
Туре:	Anticipated

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# **Ethics review**

Positive opinion Date: Application type:

10-01-2011 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