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

Gepubliceerd: 10-01-2011 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28106

Bron
NTR

Aandoening

Critical limb ischemia

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Critical limb ischemia;

2. No option for conventional revascularization;

3. Written informed consent;

4. Expected life expectancy > 1 year.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	12-01-2011
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-01-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A