

Treatment of ARA290 in neuropathic pain patients.

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The hypothesis is that the novel drug ARA290 is effective in alleviating neuropathic pain caused by small fiber neuropathy in sarcoidosis patients.

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

Samenvatting

ID

NL-OMON28997

Bron

NTR

Verkorte titel

ARA290 trial

Aandoening

- sarcoidosis
- small fiber neuropathy

Ondersteuning

Primaire sponsor: The study is performed by:

- Leiden University Medical Center, Leiden
- St. Antonius Hospital, Nieuwegein
- Maastricht University Medical Center, Maastricht

Overige ondersteuning: The study is funded by Araim Pharmaceuticals, New York, US

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pain relief by VAS scores (scale 0 (no pain) to 10 (most pain imaginable) of most pain, least pain and average pain by questionnaire.

Toelichting onderzoek

Achtergrond van het onderzoek

This study is conducted to evaluate the efficiency of ARA290 in alleviating pain in patients with sarcoidosis induced painful neuropathy and to predict treatment response by quantitative sensory testing (QST). Prior to the study, the patients neuropathy status will be evaluated by a QST protocol. Next, patients will be treated with either ARA290 (n=12) or placebo (n=12) three times a week for 4 consecutive weeks. All endpoints are evaluated by questionnaires on a weekly basis, which can be filled in online.

Doel van het onderzoek

The hypothesis is that the novel drug ARA290 is effective in alleviating neuropathic pain caused by small fiber neuropathy in sarcoidosis patients.

Onderzoeksopzet

Prior to the study, the patients neuropathy status will be evaluated by a quantitative sensory testing protocol. Next, patients are treated with either ARA290 (n=12) or placebo (n=12) three times a week for 4 consecutive weeks. All endpoints are evaluated by questionnaires on a weekly basis, which can be filled in online.

Onderzoeksproduct en/of interventie

Treatment with the novel drug ARA290 three times a week for 4 consecutive weeks. The dose for every treatment day will be 2 mg. The control group will receive a placebo.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients diagnosed with sarcoidosis induced small-fiber neuropathy;
2. A pain score of 5 or higher;
3. Age between 18 and 75 years;
4. Being able to give written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;
2. Use of erythropoietin;
3. Current use of anti-TNF or use within the passed six months;
4. Unable to give written informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-10-2011
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	27-09-2011
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	NL2934
NTR-old	NTR3081
Ander register	METC : P10-136C
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A