Het effect van ARA290 op de regeneratie van zenuwvezels bij patienten met sarcoidose en dunne vezelneuropathie.

No registrations found.

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

Summary

ID

NL-OMON22194

Source
Nationaal Trial Register

Health condition

sarcoidosis
small fiber neuropathy
pain
eye exams
skin biopsy

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Airaim pharmacy

Intervention

Outcome measures

Primary outcome

1. Change in epidermal nerve fiber density;

2. Change in cutaneous sensitivity;

3. Change in visual test, OCT, oximap and/or CCM (eye department).

Secondary outcome

1. Change in the small fiber neuropathy score;

2. Change in Brief Pain Inventory;

3. Change in 6 minut walking test.

Study description

Background summary

As ARA 290 has been demonstrated to be a neuroprotective and neurotrophic agent in a variety of preclinical in vitro and in vivo models, we expect that ARA 290 will increase the rate of epidermal nerve fiber regrowth in patients with SFN. Accordingly, we are applying for permission to study the safety and effects of ARA 290 administered subcutaneously on the rate of regeneration of the epidermal nerve fibers of patients with sarcoidosis having the diagnosis of small fiber neuropathy.

Study objective

ARA290 regenerates growth of nerve fibers and gives improvement of illness.

Study design

Weekly questionnaires and follow up of 12 weeks. Questionnaires will include BPI and SFNSL. Other methods of measurements will be: skin biopsies, 6-minute walking test, blood withdrawal and eye examination.

Intervention

Ara290 subcutuaneous during 28 days. Measurements will be done before and after this treatment. The control group will receive placebo, which exist of a saline solution subcutuaneously.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age of 18 to 65 years (inclusive);

2. Body Mass Index (BMI) between 18 and 30 kg/m2 (inclusive) and body weight between 50 kg and 90 kg (inclusive);

3. Patient is able to read and understand the written consent form, complete study-related procedures, and communicate with the study staff;

4. Patient is willing to comply with study restrictions;

5. Diagnosis of sarcoidosis, as determined by the investigator;

6. Symptoms at screening AND at first dosing visit consistent with small fiber neuropathy with a spontaneous pain level ("Pain Now") of great than or equal to 5 and small fiber neuropathy screening list score (SFNSL; (6)) > 22, or pain < 5 and SFNSL > 37;

7. Pain defined as distal pain plus one of the following:

A. Dysparesthesias;

B. Burning/painful feet worsening at night;

C. Intolerance of sheets or clothes touching the legs or feet.

Exclusion criteria

1. Clinically relevant abnormal history of physical and mental health, as determined by medical history taking and physical examinations obtained during the screening visit and/or prior to the administration of the initial dose of the study drug (as judged by the investigator);

2. A semi recumbent systolic blood pressure of >150 mmHg and/or diastolic blood pressure of > 90 mmHg at screening;

3. History of alcoholism or substance abuse within three years prior to screening;

4. Positive pregnancy test;

5. Male patients habitually using more than 21 units of alcohol per week and female patients using more than 14 units of alcohol per week;

6. Male patient is unable/unwilling to use a medically acceptable method of contraception throughout the entire study period. Female patient is not using oral contraceptives, or is not post-menopausal (last menstrual period > 2 years ago and FSH > 25 IU/L), or surgically sterilized;

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

8. Patient that received a vaccination or immunization within the last month;

9. 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;

10. Patient has undergone major surgery within three months prior to screening;

11. Donation or loss of blood (> 500 mL) within 3 months prior to screening;

12. Inadequate venous accessibility as judged by clinicians (physician or nurse);

13. Inability or unwillingness to self-administer ARA 290 via subcutaneous injections;

14. Quantitative sensory testing not consistent with small fiber neuropathy;

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-07-2012
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-08-2012
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	NL3425
NTR-old	NTR3575
Other	METC LUMC : P12084
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A