

Effects of ARA 290 on the regrowth of epidermal nerve fibers in normal volunteers and patients with sarcoidosis

Published: 17-04-2012

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In this study we will assess the effect of ARA290 on nerve damage by taking 4 skin bipsies during treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational invasive

Summary

ID

NL-OMON39192

Source

ToetsingOnline

Brief title

Effect of ARA290 on the regrowth of epidermal nerve fibers

Condition

- Peripheral neuropathies

Synonym

small fiber neuropathie AND

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Araim Pharmaceuticals.,Araim, Ossining NJ USA

Intervention

Keyword: ARA290, nerve fibers, regrowth, sarcoidosis

Outcome measures

Primary outcome

Nerve biopsy results

Secondary outcome

Pain scoring

Study description

Background summary

Patients with sarcoidosis and suffering from neuropathy have abnormalities of their peripheral nerve endings causing severe pain. ARA290 is a therapy aimed at restoration of these nerve endings. In this study we will assess the effect of ARA290 on nerve damage by taking 4 skin biopsies during treatment.

Study objective

In this study we will assess the effect of ARA290 on nerve damage by taking 4 skin biopsies during treatment.

Study design

Double-blind, placebo controlled

Study burden and risks

Taken the daily sq injections and 4 biopsies, we consider the burden/risk to be moderate. No long-term effects are to be expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

sarcoidosis

small fiber neuropathy

Exclusion criteria

BMI >30

Study design

Design

Study phase: 2

Study type: Observational invasive

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2012
Enrollment:	36
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ARA290
Generic name:	ARA290

Ethics review

Approved WMO	
Date:	17-04-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	02-07-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	18-03-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
EudraCT	EUCTR2012-001492-37-NL
CCMO	NL40277.058.12