A double blind, placebo controlled Phase 2 dose ranging study of the effects of ARA 290 on corneal nerve fiber density and neuropathic symptoms of subjects with sarcoidosis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immune disorders NEC
Study type	Interventional

Summary

ID

NL-OMON38804

Source
ToetsingOnline

Brief title
DOSARA

Condition

- Immune disorders NEC
- Peripheral neuropathies

Synonym
chronic pain in sarcoidosis patients, Sarcoid neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: ARAIM Pharmaceuticals
Source(s) of monetary or material Support: Ministerie van OC&W,ARAIM Pharmaceuticals

Intervention

Keyword: ARA290, chronic pain, neuropathy, sarcoidosis

Outcome measures

Primary outcome

To study the effect on cornea nerve fiber density.

Secondary outcome

Secondary objectives are to assess:

1) The effect of different doses of ARA 290 on Intraepidermal Nerve Fiber

Density (IENFD) of the ankle

2) the effect of different doses of ARA 290 on neuropathic symptoms in subjects

with sarcoidosis

3) the effects of ARA 290 on general health and well-being, and 6 minute walk

test, .

4) the safety of different doses ARA 290 administered subcutaneously (SC) daily

for 28 days

Exploratory objectives are to assess:

1) the effects of ARA 290 quantitative sensory testing, and on cardiac

autonomic function (heart rate variability; R-R and QT intervals)

Study description

Background summary

Neuropathic pain is very difficult to treat and causes much suffering. A new option to treat this pain is with ARA290, an anti-inflammatory substance, which has shown clear analgetic effects in experimental animals and in previous human studies. ARA290 is an EPO analogue but does not affect the hematopoietic system.

Study objective

ARA290 is a new drug against neuropathic pain and was succesfully tested in previous studies on patients with neuropathic pain due to diabetes and sarcoidosis. The current study involves sarcoidosis patients with pain due to neuropathy. The purpose of this study is to investigate the effect of different doses of ARA290 (1 mg, 4 mg, or 8 mg) or placebo on cornea nerve fiber density.

Study design

Double blind, randomised, placebo-controlled.

Intervention

Subcutaneous injection ARA 290 (1 mg, 4 mg, or 8 mg) or placebo daily during 28 days

Study burden and risks

Given the absence of major risks and the expected decrease in neuropathy, we believe that the advantages far outweigh the disadvantages.

Contacts

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Scientific
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US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The subjects will have to present the following criteria:
Established diagnosis of sarcoidosis with both of the following two criteria:
1) Score of 4 or greater on Brief Pain Inventory *average pain* questions (BPI; 0 (least discomfort)-10 (worst discomfort))
2) Discomfort defined as distal pain/discomfort plus one of the following: 1) dysesthesia, 2) burning/painful feet worsening at night, or 3) intolerance of sheets or clothes touching the legs or feet
AND either of the following two criteria
1) Corneal nerve fiber density reduced compared to normal (i.e., greater than 1 standard deviation less than the mean of a normative population)
2) A previous skin biopsy (obtained within the prior 2 years) showing a reduced intraepidermal nerve fiber density ((i.e., greater than 1 standard deviation less than the mean of a normal age and gender relevant population);In addition, subjects must:
* Be able to read and understand the written consent form, complete study-related procedures, and communicate with the study staff
* Be willing to comply with study restrictions
* Be willing to check in with the study center via the telephone
* Between 18 and 70 years of age (inclusive)
* Body Mass Index (BMI) < 40 kg/m2 (inclusive)
* If female of childbearing potential, a negative urine pregnancy test at screening and acceptable contraception will be maintained during the screening and dosing period and 1 month beyond. Acceptable contraception consists of hormonal methods such as oral, implantable, injectable, or transdermal contraceptives for a minimum of 1 full cycle (based on the subject*s usual menstrual cycle period) before study entry, intrauterine device (IUD), or

double-barrier method (condoms, sponge, diaphragm, or vaginal ring with spermicidal jellies or cream).
* Able to complete self-administered questionnaires (RAND-36, SFNSL, BPI, COMPASS-31, FAS, NPSI)
* Refrigerator and freezer at home for storage of study medication.

Exclusion criteria

The subjects should not present any of the following criteria:
* Medical history of clinically relevant physical and mental health condition other than conditions related to sarcoidosis, as judged by the investigator
* Clinically relevant abnormal laboratory results, vital signs, or physical findings other than conditions related to sarcoidosis or could interfere with conduct of 6-minute walk assessment (as judged by the investigator)
* Other medical conditions known to be associated with small nerve fiber loss, except for diabetes in good control (as judged by the investigator)
Known clinically relevant abnormalities in ECG (as judged by the investigator)
* Illicit drug abuse or excessive alcohol consumption (as judged by the investigator)
* History of serious malignancy within the last 5 years other than a basal cell or squamous cell carcinoma that has been removed
* History of severe allergies, or has had an anaphylactic reaction or significant intolerability to prescription or non-prescription drugs or food (as judged by the investigator)
* Anti-TNF therapy or other biological anti-inflammatory agents administered within the 6 months prior to screening.
* Use of erythropoiesis stimulating agents within the two months prior to screening or during the trial
* 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 in the calendar year preceding study enrollment
* Inadequate venous accessibility as judged by clinicians (physician or nurse)
* Inability or unwillingness to self-administer ARA 290 via subcutaneous injections (or not have access to home health care for assistance in administration)
* If female, pregnant or breast-feeding
* 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 phase: 2

Study type:	Interventional
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):	27-11-2013
Enrollment:	32
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	14-08-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	11-09-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	29-11-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	02-12-2013

Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	22-01-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	30-01-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	17-03-2014
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	EUCTR2013-003016-45-NL
CCMO	NL45854.058.13