

# ARA 290 Intravenous-Subcutaneous crossover study in normal human volunteers - PKARA Study

Published: 10-02-2012

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To measure the PK of ARA290 when given in de SQ form

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Peripheral neuropathies
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON37923

### Source

ToetsingOnline

### Brief title

PKARA study

### Condition

- Peripheral neuropathies

### Synonym

neuropathic pain, pain

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

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

## Intervention

**Keyword:** ARA290, Pharmacokinetics

## Outcome measures

### Primary outcome

Plasma concentration of ARA290

### Secondary outcome

NA

## Study description

### Background summary

We recently studied ARA290 in neuropathic pain patients (with sarcoidosis and DM). The results of the first open label study were very positive finding a high response rate (55-60%) with pain relief > 50% during the treatment period (P10.131). No side effects occurred. The only drawback to the treatment was the need for the intravenous treatment. This is cumbersome, and needs a doctor or nurse present during treatment. Araim Pharmaceuticals therefore decided to develop a subcutaneous formulation which allows the patient to dose him or herself without the need for an intravenous access line. Similar to insulin treatment the patient can administer the ARA290 via a SQ (subcutaneous injection). In the current study we will assess the pharmacokinetics of ARA290 given in the subcutaneous formulation and compare this to an intravenous injection in a small group of volunteers.

### Study objective

To measure the PK of ARA290 when given in the SQ form

### Study design

Open label  
Cross-over

### Study burden and risks

Minimal if any

## Contacts

### Public

Leids Universitair Medisch Centrum

Albinusdreef 2  
2333 ZA Leiden  
NL

### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Healthy volunteers in the age range of 18-65 years

### 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. Negative pregnancy test
5. Male subjects habitually using more than 21 units of alcohol per week and female subjects using more than 14 units of alcohol per week;
6. Subject was a smoker or has used nicotine/nicotine-containing products within 3 months prior to screening;
7. Use of medication during the study period;
8. Subject is unable to refrain from food and drinks containing a xanthine (e.g. chocolate, cola, coffee or tea) during the study days
9. Male subject is unable/unwilling to use a medically acceptable method of contraception throughout the entire study period. Female subject is not using oral contraceptives, or is not post-menopausal (last menstrual period > 2 years ago and FSH > 25 IU/L), or surgically sterilized;
10. Subject has a history of severe allergies, or has had an anaphylactic reaction or significant intolerance to prescription or non-prescription drugs or food;
11. Subject has a history of syncopal episodes;
12. Subjects that received a vaccination or immunization within the last month;
13. 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;
14. Subject has undergone major surgery within three months prior to screening;
15. Donation or loss of blood (> 500 mL) within 3 months prior to screening;
16. Inadequate venous accessibility as judged by clinicians (physician or nurse);
17. 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 type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 29-03-2012

Enrollment: 6

Type: Actual

## Medical products/devices used

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

## Ethics review

Approved WMO	
Date:	10-02-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	26-03-2012
Application type:	First submission
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	EUCTR2012-000390-23-NL
CCMO	NL39602.058.12