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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	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, Phramacokinetics

Outcome measures

Primary outcome

Plasma concentration of ARA290

Secondary outcome

NA

Study description

Background summary

We recently studied ARA290 in neuropathic pain patients (with sacrcoidosis 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 de SQ form

Study design

Open label
Cross-over

Study burden and risks

Minimal if any

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

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 intolerability 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