Intranasal Pharmacokinetics of ARA 290 in Normal Human Volunteers

Published: 30-01-2013
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To measure the plasma conc. of ARA 290 in healthy volunteers

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

Summary

ID

NL-OMON38517

Source
ToetsingOnline

Brief title
INPARA

Condition

- Other condition

Synonym
nerve pain, neuropathic pain

Health condition

neuropathische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ARAIM Pharma. ,ARAIM Pharmaceuticals

Intervention

Keyword: ARA290, pain, Pharmacokinetics

Outcome measures

Primary outcome

Plasma concentration of ARA 290 over time

Secondary outcome

none

Study description

Background summary

ARA290 is currently being used experimentally in the treatment of neuropathic pain. The administration is either intravenously or subcutaneously. This complicates the treatment process. In order to facilitate the administration, the intranasal route is studied in this study. Should this succeed then this route will be used in future clinical studies.

Study objective

To measure the plasma conc. of ARA 290 in healthy volunteers

Study design

Open, observational

Study burden and risks

The burden is low taken the results of previous studies. Benefit to the participant is absent.

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

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);;4. Subject is able to read and understand the written consent form, complete study-related procedures, and communicate with the study staff;;5. Subject is willing to comply with study restrictions

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 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 phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2013
Enrollment:	6
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	30-01-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	15-03-2013
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	EUCTR2012-005843-26-NL
CCMO	NL43158.058.13