A randomized, double-blind, placebo-controlled Phase I study to evaluate the safety and tolerability of intrathecally administered single ascending bolus doses of Xen2174 in healthy subjects

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To evaluate the overall safety and tolerability of intrathecally administered single ascending bolus doses of Xen2174 in healthy subjectsTo evaluate the effects of Xen2174, following its administration as a single intrathecal bolus, on EEG activity...

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

Summary

ID

NL-OMON32600

Source
ToetsingOnline

Brief title
Phase I study with intrathecally administered single doses of Xen2174.

Condition

- Other condition

Synonym
Pain

Health condition

Pijn

Research involving
Human

Sponsors and support

Primary sponsor: Xenome Ltd.
Source(s) of monetary or material Support: Xenome Ltd.

Intervention

Keyword: Intrathecally, Pain, Phase I, Xen2174

Outcome measures

Primary outcome

To evaluate the overall safety and tolerability of intrathecally administered

single ascending bolus doses of Xen2174 in healthy subjects

Secondary outcome

To evaluate the effects of Xen2174, following its administration as a single

intrathecal bolus, on EEG activity (continuously until 24 hours post-dose, and

at selected intervals thereafter through the final follow-up visit)

To analyze plasma concentrations of Xen2174 at selected time points.

Study description

Background summary

Xen2174 is an investigational drug that is being developed to treat pain that does not adequately respond to analgesic and is a peptide that binds to the NorEpinefrine Transporter (NET) in the central nervous system, which is involved in case of pain.

Study objective

To evaluate the overall safety and tolerability of intrathecally administered single ascending bolus doses of Xen2174 in healthy subjects
To evaluate the effects of Xen2174, following its administration as a single

intrathecal bolus, on EEG activity (continuously until 24 hours post-dose, and at selected intervals thereafter through the final follow-up visit)
To analyze plasma concentrations of Xen2174 at selected time points.

Study design

Seven groups of 5 male and infertile female subjects (20 in total) will take part in this study. The study will comprise a medical screening (possibly comprising various visits), one three-day stay at the Unit, two visits and finally a follow-up visit.

Intervention

Per group of 5 subjects, 4 will recieve the investigational drug and 1 will receive a placebo

Study burden and risks

The risks associated with this investigation are linked together with the possible side effects of the intrathecal dosing and the investigational product. The burden on the volunteer will continue to work with the recording periods, venapunctions and the introduction of the cannulas. All volunteers are closely monitored and supervised by experienced doctors and studystaff for possible side effects.

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

• you have given your written consent to take part in this study;
• you are between 21 and 55 years of age (inclusive);
• you are in good physical and mental health;
• your body weight must be appropriate in relation to your height;
• for female volunteers: you are not pregnant, nor can you get pregnant (you are surgically sterile or your uterus has been removed or you have been post-menopausal - if you are over 50 years old, your last menstrual period must be at least one year ago; if you are 50 years or younger, your last menstrual period must be more than two years ago);
• no abnormalities are diagnosed during the screening.

Exclusion criteria

• you drink more than 21 (male) or 14 (female) units of alcohol per week;
• you are (or have been) taking illegal drugs and/or are (or have been) using alcohol to excess;
• you have used prescribed medication in the 7 days before admission;
• you have used over the counter medication in the 7 days before admission (exception paracetamol);
• you have used medication, which makes you unsuitable to participate in this study;
• females: if you are pregnant or lactating;
• you have an abnormal EEG at screening or in the past;
• you have taken part in another clinical drug study during the last 3 months prior to the study;
• you have donated blood in the three months before admission;
• you are Hepatitis B, C or HIV positive;
• you or your releatives have or had epilepsy;
• you have lost you consciences in the past (exception fainting);
• you have had several blow to the head which could lead to brain damage;
• you had meningitis or any other dissease that could be of influence on the brain;
• you had chemotherapy or radiotherapy;
• you have a bood difficiency;

• you or your relatives have had a back abnormality, which makes you unsuitable to participate in this study;
• you had an operation to the back, which makes you unsuitable to participate in this study;
• you have a skin abnormality at the injection site;
• you have received Xen2174 in the past;
• you have a clinically significant medicine allergy or sensitivity;
• you are not suitable to participate in this study according to the investigator;

Study design

Design

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):	01-10-2009
Enrollment:	35
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Xen2174
Generic name:	Xen2174

Ethics review

Approved WMO

Date:	04-09-2009

Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-09-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-10-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-10-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-12-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	17-12-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2009-014243-37-NL
CCMO	NL29372.040.09