A RANDOMIZED, DOUBLE BLIND, PLACEBO CONTROLLED, CROSS-OVER, ASCENDING SINGLE ORAL DOSE, SAFETY, TOLERABILITY AND PHARMACOKINETIC STUDY OF CB-189,625 IN HEALTHY MALE SUBJECTS.

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Primary: to assess the safety and tolerability of one oral dose of CB-189,625 at 6 dose levels in healthy male volunteers.Secondary: to determine the plasma pharmacokinetic profile of one oral dose of CB 189,625 at 6 dose levels in healthy...

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

Summary

ID

NL-OMON37794

Source
ToetsingOnline

Brief title
CB-189,625 SAD study

Condition

- Other condition

Synonym
acute and chronic pain

Health condition

acute en chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Cubist Pharmaceuticals, Inc
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: 625, acute and chronic pain, CB-189

Outcome measures

Primary outcome

Safety and tolerability: AEs, clinical laboratory data, vital sings, ECG,

physical examination

Secondary outcome

Pharmacokinetics: concentrations of CB-189,625, PK parameters

Study description

Background summary

CB-189,625 is a new investigational compound that may eventually be used for the treatment of acute and chronic pain, potentially decreasing the need for opioids (narcotics). This is the first time that this compound will be given to humans.

Study objective

Primary: to assess the safety and tolerability of one oral dose of CB-189,625 at 6 dose levels in healthy male volunteers.
Secondary: to determine the plasma pharmacokinetic profile of one oral dose of CB 189,625 at 6 dose levels in healthy volunteers.

Study design

This is a randomized, double-blind, placebo-controlled, cross-over, single dose, safety, tolerability and pharmacokinetic study of 6 ascending doses of CB-189,625 in two cohorts of healthy male volunteers. The first cohort of nine subjects (Cohort 1) will be sequentially enrolled into 3 of 6 dosing periods (Dose Levels 1, 3, and 5). The remaining cohort of nine subjects (Cohort 2) will be enrolled in the other 3 dosing periods (Dose Levels 2, 4, and 6). Each subject will receive one dose of placebo and two different doses of CB-189,625 over the course of their participation in all three dosing periods.

Procedures and assessments:
Pre-screening, throughout the study and safety days: demographics, medical history, drug and alcohol screen, vital signs (including body weight and height, supine systolic and diastolic blood pressure, pulse rate, respiratory rate and body temperature), 12 lead electrocardiogram (ECG), serology (HBsAg, anti HCV and anti-HIV 1/2), clinical laboratory (including clinical chemistry, hematology and urinalysis), physical examination, adverse events (AEs), previous medication, hot/cold sensation and audiometry.

Blood sampling: Blood for plasma concentration of CB-189,625 and its metabolites.
Urine sampling: Urine for analysis of levels of CB-189,625 and its metabolites will be collected.

Intervention

Cohort 1:
period 1: a single oral dose of 200 mg CB-189,625 or placebo.
period 3: a single oral dose of 800 mg CB-189,625 or placebo.
period 5: a single oral dose of 1600 mg CB-189,625 or placebo.

Cohort 2:
period 2: a single oral dose of 400 mg CB-189,625 or placebo.
period 4: a single oral dose of 1200 mg CB-189,625 or placebo.
period 6: a single oral dose of 2000 mg CB-189,625 or placebo.

Each subject will particpate in three periods, receiving two different doses of CB-189,625 and one dose of placebo.

Study burden and risks

As CB-189,625 will be administered to man for the first time in this study, to date adverse effects in man have not been reported. CB-189,625 has been studied in animals (rats, dogs and monkeys). The most important adverse events reported from these animal studies were: diarrhea, changes in clinical laboratory parameters including cholesterol, liver enzymes, red blood cell indices, and urine output, and changes to the vital signs and ECG. These events occurred at

much higher doses in animals than will be used in man. One of the inactive ingredients, hydroxypropyl-beta-cyclodextrin (HPCD) that is used in both the CB-189,625 compound and the placebo compound can cause diarrhea and stomach discomfort after multiple high daily doses. The single dose of HPCD that you receive in this study is not anticipated to cause any discomfort.
With the doses used in this study no serious adverse effects are expected. The occurrence of known or other effects cannot be excluded.

Registration af adverse effects: During the entire investigation all adverse effect you report will be documented.

Blood draw, indwelling canula: During this study less then 400 ml of blood will be drawn. It is anticipated that in every period an indwelling canula will be used and approximately 4 blood draws will be drawn by direct puncture of the vein.

Collection of urine: All urine will be collected until 48 hours after administration of CB-189,625 or placebo (thus until Day 3 of each period).

Heart trace (ECG*s): ECG*s will be made regularly, once before and 4 times after each time you are administered CB-189, 625 or placebo.

Hot /Cold sensation: During the 24 hours after administration of CB-189,625 or placebo (thus until Day 2 of each period), you will be regularly tested on your perception of hot and cold materials on your skin.

Audiometry: Before and 1 hour after administration of CB-189,625 or placebo your hearing will be tested

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 male subjects
18-55 yrs, inclusive
BMI: 18.0-30.0 kg/m2, inclusive
non-smoking

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-02-2012
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	03-01-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-01-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2011-004932-73-NL
CCMO	NL39026.056.11