A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, ASCENDING MULTIPLE DOSE, SAFETY, TOLERABILITY PHARMACODYNAMIC AND PHARMACOKINETIC STUDY OF BCI 838 IN HEALTHY ADULT SUBJECTS

Published: 24-01-2012
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Primary: To evaluate the safety and tolerability following oral administration of multiple doses of BCI-838 in healthy male and female subjects Secundary:To determine the pharmacokinetic profile of multiple oral doses of BCI-838 in healthy male and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON37895

Source
ToetsingOnline

Brief title
BCI-838 MAD study, tolerabilty, uptake and distribution study

Condition

- Mood disorders and disturbances NEC

Synonym
depression, mood disorders

Research involving

Human

Sponsors and support

Primary sponsor: BrainCells Inc.
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: BCI-838, Multiple acsending dose (MAD), pharmacodynamics, Pharmacokinetics, Tolerabilty

Outcome measures

Primary outcome

Safety and tolerabilty of BCI-838

Secondary outcome

Pharmacokinetic of BCI-838 by analysis of plasma concentrations of BCI-838 and

metabolite BCI-632

and Pharmacodynamic of BCI-838 by analysis/registration of brain activity (EEG)

Study description

Background summary

BCI-838 is a new investigational compound that may eventually be used for the treatment of mood disorders (for example depression). BCI-838 is not registered as a drug but has been given to humans before.

Study objective

Primary:
To evaluate the safety and tolerability following oral administration of multiple doses of BCI-838 in healthy male and female subjects

Secundary:
To determine the pharmacokinetic profile of multiple oral doses of BCI-838 in healthy male and female subjects
To assess the pharmacodynamic effects of BCI-838 on the central nervous system

using quantitative electroencephalogram (EEG) analysis

Study design

A randomized, double blinde, placebo-controlled, multi ascending dose, safety, pharmacokinetic and pharmacodynamic study of BCI-838 in healthy male and female adult subjects.

The study will consist of 30 subjects divided over 3 groups (10 subjects per group). The subjects De vrijwilligers will receive a dose of between 100 to 900 mg BCI-838 in the form of a capsule.
The dose level for group 1 will most likely be 100 mg. However, the exact dose level will be determined based on ongoing single ascending dose studies. The dose levels for the subsequent groups (2 and 3) will be increased to a maximum of 900 mg and only if the lower dose of the previous group was found to be well tolerated and after receipt of no objection by the local Ethics Committee.

Procedures and assessments during the study:
Screening , follow-up and during study: demographics, body weight and height (including body mass index calculation),
medical history, drug and alcohol screen, cotinine test, blood sampling for serology (HBsAg, anti HCV and anti-HIV 1/2),
DNA test, clinical chemistry, hematology, pharmacokinetics, CSSRS, Heart trace (ECG*s), and registration of brain activity (EEG)

Intervention

The study will consist of 3 groups, each group will will stay in the clinical research centre for 11 days (10 nights).
During the study subjects will receive BCI-838 or inactive formulation (placebo) after a high fat breakfast with 240 mL of tap water once daily on 7 subsequent days. Per group 8 participants will receive BCI-838 and 2 participants will receive placebo. Whether subjects will receive the active drug or placebo will be determined by chance.
The participant, nor the investigator knows if BCI-838 will be dosed; we call this *the study is blinded*. However, information on the administration of study medication and placebo will be present in the clinical research facility, in sealed envelopes, which can be opened in case of emergency.
The participant will receive the study drug after a high fat breakfast, which they will need to finish completely. The high fat breakfast will start 30 minutes prior to dosing and will need to be finished 10 minutes prior to dosing. Sbjects will need to fast (not eat or drink anything) until 4 hours after drug administration, after which they will receive a lunch. After intake of the study medication, they are allowed to drink water with the exception of 2 hour prior to until 1 hour after drug administration. After dosing, subjects are not allowed to lie down for 4 hour post dose, with the exception of study

related procedures.

Study burden and risks

During the study several assessments will be conducted differing in extent and the nature of burden:
Blood draws via direct puncture or an indwelling canula: It is anticipated that for each group 2 time(s) an indwelling canula
will be used and 18 blood draws will be drawn by direct puncture of the vein. Possible side effects of an indwelling canula are pain, light bleeding, heamatoma, possibly an infection.

Heart trace (ECG*s): specifically on Days 1 and 7.

Recording of brain activity (EEG) will be performed on days 1 and 7

Columbia Suicide Severity Rating Scale (C-SSRS) will be performed during screening and follow-up and on Day 7

In previous studies with healthy volunteers, adverse events that were reported were in general mild, transient and considered not related to study drug. To date only mild headache is reported as possibly related to the study medication.

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 and female subjects
Age: 18 * 55 years, inclusive
BMI: 18 * 30 kg/m2, inclusive
Non smoker or moderate smoker (*5 cigarettes per day)

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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	24-01-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	31-01-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-03-2012
Application type:	Amendment
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	EUCTR2011-006089-41-NL
CCMO	NL39282.056.12