A PHASE I, OPEN-LABEL, FIXED-SEQUENCE, THREE-PERIOD CROSSOVER TRIAL TO EVALUATE THE PHARMACOKINETICS OF TWO DIFFERENT TABLET FORMULATIONS OF BCI 952 COMPARED TO THE OVER-ENCAPSULATED BCI-952 PRODUCT COMPONENTS IN HEALTHY MALE SUBJECTS

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PrimaryTo evaluate the pharmacokinetics of two different tablet formulations of BCI-952 compared to the over-encapsulated BCI-952 product components.SecondaryTo evaluate the safety and tolerability following the administration of two different...

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

Summary

ID

NL-OMON36120

Source
ToetsingOnline

Brief title
BCI-952 three-period crossover bioequivalence study

Condition

- Mood disorders and disturbances NEC

Synonym
depression

Research involving
Human

Sponsors and support

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

Intervention

Keyword: BCI-952, depression

Outcome measures

Primary outcome

Pharmacokinetics

Safety

Tolerability

Secondary outcome

n/a

Study description

Background summary

BCI-952 is a new combination of two registered medications, buspirone and melatonin SR (slow release), that may eventually be used for the treatment of Major Depressive Disorder (MDD). Buspirone is a psychoactive drug and is generally used for the treatment of anxiety disorders. Melatonin is generally prescribed as a sleep aid. Until now, BCI-952 was administered in other studies as two separate capsules. BrainCells Inc has developed two new formulations of BCI-952 tablets, so that a single tablet contains buspirone as well as melatonin SR. Both tablets contain the same amount of buspirone and the same amount of melatonin. The two tablets also contain the same additive; however, the proportion of the additives differs between the two new formulations. An additive is an inactive substance which is added to the drug

to create volume and make it possible to form a tablet. The additives may also affect the slow release nature of the melatonin.
This new combination of registered medications is not registered as a drug but has been given to humans before.

Study objective

Primary
To evaluate the pharmacokinetics of two different tablet formulations of BCI-952 compared to the over-encapsulated BCI-952 product components.

Secondary
To evaluate the safety and tolerability following the administration of two different tablet formulations of BCI-952 and the over-encapsulated BCI-952 product components.

Study design

Design
An open-label, fixed sequence, three-period crossover study in eight healthy male subjects receiving a single oral dose of BCI 952 in 3 different formulations (two new tablet formulations compared to the over encapsulated tablets/caplets of two separate components). For each individual subject, there will be a washout of at least five days between dosing in each period.

Procedures and assessments
-Screening and follow-up:clinical laboratory, physical examination, 12-lead ECG (in triplicate), vital signs (including pulse rate, systolic and diastolic blood pressure, respiratory rate and oral body temperature); at eligibility screening: medical history, drug screen, HBsAg, anti HCV, anti-HIV 1/2; to be repeated upon each admission: 12-lead ECG, vital signs and clinical laboratory (including drug screen)

-Observation period:three periods in clinic from -18 h up to 24 h after drug administration on Day 1

-Blood sampling:for pharmacokinetics of plasma melatonin and buspirone: pre-dose and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 16 and 24 h post dose

-Safety assessments:adverse events: throughout the study; vital signs (including pulse rate, systolic and diastolic blood pressure, respiratory rate and oral body temperature): pre-dose and 1, 4, 12 and 24 h post-dose

-Bioanalysis:analysis of melatonin and buspirone samples using a validated method by PRA

Intervention

Treatments
Period 1: a single dose of BCI-952 consisting of an over-encapsulated commercially available buspirone IR 15 mg tablet and an over-encapsulated commercially available melatonin SR 3 mg caplet
Period 2: a single oral dose of BCI-952 new formulation #F8, containing buspirone IR 15 mg and melatonin SR 3 mg as a single bi-layer tablet
Period 3: a single oral dose of BCI-952 new formulation #F13, containing and buspirone IR 15 mg and melatonin SR 3 mg as a single bi-layer tablet

Study medication: BCI-952
Active substance:buspirone and melatonin
Activity: neurogenesis
Indication:depression
Strength:15 mg buspirone IR and 3 mg melatonin SR
Dosage form:single bi-layer tablet or over-encapsulated tablet/caplet

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection

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 volunteer
Age : 18 * 40 years, inclusive
Body mass index (BMI) : 18-30 kg/m2, inclusive
non-smoking or smoking less then or equal to 5 cigarettes/day

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS. In case of participation in another drug study within 60 days before the start of the study. In case of donating any blood or significant loss of blood within 60 days of the start of drug dosing.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	14-04-2011
Enrollment:	8
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	buspirone (IR)
Generic name:	buspar
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	melatonin (SR)
Generic name:	Circadin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-03-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-03-2011
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	EUCTR2010-024645-75-NL
CCMO	NL35980.056.11