A RANDOMIZED, SINGLE-CENTER, OPEN-LABEL, 5-WAY CROSSOVER, SINGLE-DOSE BIOAVAILABILITY/BIOEQUIVALENCE COMPARISON OF BRIVARACETAM ORAL TABLETS (10MG, 50MG, 75MG, AND 100MG) AND BRIVARACETAM INTRAVENOUS BOLUS INJECTION (100MG) IN HEALTHY VOLUNTEERS

Published: 17-01-2013
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Primary objective:To assess the BE under fasted conditions of BRV 10mg, 75mg, and 100mg oral tablets of commercial formulation vs BRV 50mg oral tablet(reference) of clinical development formulation,To assess the BA under fasted conditions of BRV…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON38511

Source
ToetsingOnline

Brief title
Brivaracetam BA/BE study

Condition

- Seizures (incl subtypes)

Synonym
attacks, epileptic seizures

Research involving
Human

Sponsors and support

Primary sponsor: UCB Pharma
Source(s) of monetary or material Support: Pharmaceutische industrie.

Intervention

Keyword: BIOAVAILABILITY/BIOEQUIVALENCEHEALTHY VOLUNTEERS, BRIVARACETAM

Outcome measures

Primary outcome

Pharmacokinetics: plasma drug concentrations, pharmacokinetic parameters

Safety: adverse events, vital signs, ECG-parameters, laboratory parameters,

physical examination.

Secondary outcome

Pharmakinetics parameters: analysis of variance on Cmax and AUC, other

parameters descriptive statistics.

Safety parameters: descriptive statistics.

Study description

Background summary

Brivaracetam (BRV) is a new investigational compound that may eventually be used for the treatment of epileptic seizures. BRV is not yet approved as a drug but has been given to humans before.

Study objective

Primary objective:
To assess the BE under fasted conditions of BRV 10mg, 75mg, and 100mg oral tablets of commercial formulation vs BRV 50mg oral tablet (reference) of clinical development formulation,

To assess the BA under fasted conditions of BRV 100mg 2-minute iv bolus injection vs BRV 100mg oral tablet

Secundary objective:
The secondary objective is to gain additional information about the safety and tolerability of BRV.

Study design

Design:
This is a randomized, single-center, open-label, 5-way crossover, single-dose, BE/BA Phase 1 study in 25 (planned) healthy subjects.

Procedures and assessments
Screening and follow-up:
clinical laboratory, physical examination, ECG, vital signs, serum pregnancy test (females only); at eligibility screening: medical history, urine drug and alcohol screening tests, height, weight, HBsAg, anti HCV, anti-HIV 1/2, FSH (females only)

Each admission:
vital signs, urine dip-stick pregnancy test (only for females of childbearing potential)

Observation period:
each period in clinic from up to 48 hrs after drug administration

Blood sampling:
for pharmacokinetics: predose, 5min, 15min, 30min, 1h, 1.5h, 2h, 3h, 6h, 9h, 12h, 24h, 36h, and 48h post dose.

Safety assessments:
Physical examinations, ECG, vital signs, clinical laboratory and AEs.

Intervention

Strength:
Tablets of 10, 50, 75 and 100 mg; 100mg iv bolus 10mg/mL injection

Dosage form:
Oral Tablets of 10, 50, 75 and 100 mg; 100mg iv bolus 10mg/mL injection using a syringe and slow push in 2 minutes

The order in which the treatments are given in the 5 periods may differ between volunteers.

Study burden and risks

During the investigation, various assessments can be experienced as more or less stressful.

Blood draw, indwelling canula:
During this study blood will be drawn. Each period 1 time an indwelling canula will be used and a number of blood draws will be drawn by direct puncture of the vein. The insertion of the canula may be associated with pain, minor bleeding, bruising, possible infection.

Also there will be a second canula inserted in the other arm for the administration of the iv bolus injection. This may be associated with the same side effects as reported above.

In previous studies with BRV in healthy subjects, the most common adverse effects tended to appear rapidly after the first study drug intake were dizziness, a strong desire for sleep, fatigue, feeling drunk, euphoric mood, headache, nausea, vertigo, lack or loss of strength and energy (weakness). BRV belongs to a group or *class* of medications known as anti-epileptics. An increased risk of suicidal ideation (thoughts of harming yourself or committing suicide). Suicide attempt and completed suicide have been noticed in people who take anti-epileptic medications and also in people who have a severe or long term of epilepsy. With the doses used in this study no serious adverse effects are expected. The occurrence of known or other effects cannot be excluded.

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 males and females
18-55 years, incl.
BMI 18.0-30.0 kg/m2 incl.

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
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2013
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	n/a
Generic name:	Brivaracetam

Ethics review

Approved WMO Date:	17-01-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-01-2013
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	EUCTR2012-001358-25-NL
CCMO	NL42856.056.13