

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Seizures (incl subtypes)
<b>Study type</b>	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**

Pharmakinetiks 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

Secondary 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**

### **Public**

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### **Scientific**

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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/m<sup>2</sup> 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