SINGLE-CENTER, OPEN-LABEL, SINGLE-DOSE STUDY OF THE EXCRETION BALANCE, PHARMACOKINETICS, AND METABOLISM OF 14C-LABELED UCB0599 AND UCB2713

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON43504

Source
ToetsingOnline

Brief title
Excretion balance and PK study of 14C UCB0599 and UCB2713

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease.

Research involving
Human

Sponsors and support

Primary sponsor: UCB Biopharma SPRL
Source(s) of monetary or material Support: Farmaceutische Industrie

Intervention

Keyword: 14C, Parkinson, UCB0599, UCB1332, UCB2713

Outcome measures

Primary outcome

Please refer to the protocol for more details, below the two main criteria:

- To evaluate the excretion balance of 14C labeled UCB0599 and 14C labeled UCB2713 administered orally together with oral UCB1332 (Part A)

- To evaluate the plasma and CSF PK profiles of UCB0599 and UCB2713 and their respective desmethyl metabolites when administered intravenously as 14C-labeled tracer together with an oral loading dose of UCB1332 (Part B)

Secondary outcome

• To determine the protein binding of total radioactivity, UCB0599 and UCB2713 and their respective desmethyl metabolites, in plasma and CSF, if permitted by analytical sensitivity (Part B)

• To document the single dose safety and tolerability of UCB1332.

Study description

Background summary

UCB1332 is a new investigational compound that may eventually be used for the treatment of Parkinson*s disease. Alpha synuclein is a protein that is present in the human body, especially in the brain where it plays a role in processes in the brain cell and in communication between brain cells. In patients with Parkinson*s disease, accumulation of this protein takes place which disturbs

the normal processes in and between brain cells. UCB1332 interacts with alpha synuclein and thereby prevents the accumulation of the protein and is therefore considered to reduce the intensity of the symptoms of Parkinson*s disease. UCB1332 is in development and is not registered as a drug but has been given to humans before.

Study objective

The purpose of the study is to investigate how quickly and to what extent UCB0599 and UCB2713 are absorbed, distributed, metabolized (broken down) and excreted from the body (this is called pharmacokinetics). Since UCB0599 and UCB2713 will be radiolabeled in Parts A and B, UCB0599 and UCB2713 can be traced in blood (Parts A and B), cerebrospinal fluid (Part B only), and urine and feces (Part A only). Another purpose in both Parts A and B of the study is to investigate to what extent the administered study compounds are tolerated.

Study design

Part A:
The study will consist of 1 period during which the volunteers will stay in the research centre from Day -1 to at least Day 8. If on Day 8, the radioactivity levels in the urine and feces are above pre-defined levels, the volunteers will have to stay in the clinical research center, and the radioactivity levels in the urine and feces will be checked every day until a maximum of Day 11.

Part B:
The study will consist of 1 period during which the volunteers will stay in the clinical research center from Day -1 to Day 3. It may be decided by the medical doctor that the volunteer will need to stay in the clinical research center for a longer period of time.

Intervention

The study will be performed in 2 parts in a total of 14 healthy male volunteers.

Part A will consist of 8 volunteers. All 8 volunteers will receive 30 milligrams UCB1332 as 2 oral capsules. 4 volunteers in Group 1, 1 of the 2 capsules with UCB1332 will also contain a small dose of 20 micrograms of UCB0599 which will be labeled with 14-Carbon. For the 4 volunteers in Group 2, 1 of the 2 capsules with UCB1332 will also contain a small dose of 20 micrograms of radiolabeled UCB2713.

Part B will consist of 6 volunteers; 3 volunteers will receive 30 milligrams UCB1332 and a small dose of 20 micrograms of 14C UCB0599 as an intravenous infusion. 3 volunteers will receive 30 milligrams UCB1332 and a small dose of

20 micrograms of 14C UCB2713 as an infusion in a vein.

Study burden and risks

Please refer to the protocol and IB for treatment related adverse events.

Adverse events related to procedures: Pain, minor bleeding, bruising and possible infection

Contacts

Public
UCB Biopharma SPRL

Allée de la Recherche 60
Brussels B-1070
BE
Scientific
UCB Biopharma SPRL

Allée de la Recherche 60
Brussels B-1070
BE

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 years
50 - 100 kg
BMI 18 - 30 kg/m2
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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2015
Enrollment:	14
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	UCB1332
Generic name:	UCB1332

Ethics review

Approved WMO

Date:	17-11-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-11-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-02-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-02-2016
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	EUCTR2015-003591-68-NL
CCMO	NL55619.056.15