A phase 1b study to evaluate the pharmacokinetics and safety of CLE-600 in patients with Parkinson*s disease

Published: 10-11-2022
Last updated: 07-04-2024

In this study we will investigate how quickly and to what extent carbidopa and levodopa are absorbed, transported, and eliminated from the body when administered as the study compound, the CLE-600 oral system. We will also investigate the safety and…

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

Summary

ID

NL-OMON53497

Source
ToetsingOnline

Brief title
CLE-600 PK and safety study

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Clexio Biosciences Ltd
Source(s) of monetary or material Support: Pharmaceutical industry

Intervention

Keyword: CLE-600, PK, Safety

Outcome measures

Primary outcome

- CD and LD PK parameters: Cmax, Tc above 450ng/ml, Tmax, AUC0-t, AUC0-inf,

t1/2, Tlag as applicable

- Safety and tolerability: Incidence of adverse events, vital signs, clinical

laboratory tests and ECG

Secondary outcome

N/A

Study description

Background summary

The CLE-600 oral system is an oral system for administration of the Parkinson*s disease (PD) medications carbidopa and levodopa. Many PD patients are treated with levodopa and carbidopa taken a few times a day to improve the symptoms of the disease.

One problem that PD patients face is the wearing off of the effect of levodopa before the next dose of medication. It can also happen in the night and early morning. The CLE-600 oral system is being developed to counteract possible wearing off in the night or early morning. The CLE-600 oral system can store multiple tablets of PD medication. After ingestion of the CLE-600 oral system the platform unfolds in the stomach and slowly releases the medication. It is estimated that the medication will be released over 8 to 10 hours. Thereafter the platform disassembles and is excreted via the stool.

Study objective

In this study we will investigate how quickly and to what extent carbidopa and levodopa are absorbed, transported, and eliminated from the body when administered as the study compound, the CLE-600 oral system. We will also investigate the safety and how well the study compound is tolerated when used

by patients with Parkinson*s disease.

The study compound is the CLE-600 oral system, which is composed of a delivery platform with carbidopa and levodopa inside. The CLE-600 oral system is folded into a capsule for swallowing, and unfolds back to a triangular shape in the stomach, which allows long-acting release of the medication.

All subjects receive a standardized meal before each oral administration of the CLE-600 oral system (either a light meal, a moderate-fat meal or a high-fat meal) during the study. We use different types of meal to further test the absorption of the study compound.

Study design

In total the volunteer will visit the research center 2 or 3 times:

Part A:
Screening: Day -21 up to Day -1
Arrival: Day 1
In-house stay: Day 1 up to Day 3
Departure: Day 3
Follow-up (if needed): Between Day 6 and Day 8

Part B:
Screening: Day -21 up to Day 1
Arrival: Day -1
In-house stay: Day -1 up to Day 3
Departure: Day 3
Follow-up (if needed): Between Day 6 and Day 8

The volunteer will be given CLE-600 with 50 mg carbidopa and 500 mg levodopa twice (one administration per evening on 2 consecutive evenings) as an oral capsule with 240 milliliters (mL) of (tap) water.

Intervention

The volunteer will be given the CLE-600 oral system which contains 50 mg carbidopa and 500 mg levodopa twice (one administration per evening on 2 consecutive evenings) as an oral capsule with 240 milliliters (mL) of (tap) water.

Study burden and risks

Blood draw
Drawing blood may be painful or cause some bruising. The use of the indwelling cannula can sometimes lead to inflammation, swelling, hardening of the vein,

blood clotting, and bleeding in the environment of the puncture site. In some individuals, a blood draw can sometimes cause pallor, nausea, sweating, low heart rate, or drop in blood pressure with dizziness or fainting.

In total, we will take not more than 325 (Part A) / 281 (Part B) milliliters (mL) of blood from the volunteer from screening to follow-up. This amount does not cause any problems in adults.

Heart tracing
To make a heart tracing, electrodes will be placed on the arms, chest and legs. Prolonged use of these electrodes can cause skin irritation.

Meals/Fasting
The standardized meals are either a standardized light meal, moderate-fat meal or high-fat meal. The volunteer must consume the whole meal. It can be difficult to consume the entire fat meals, particularly for light eaters.

If the volunteer has to fast for a prolonged time during the study, this may lead to symptoms such as dizziness, headache, stomach upset, or fainting.

Coronavirus test
Samples for the coronavirus test will be taken from the back of the nose and throat using swabs. Taking the samples only takes a few seconds, but can cause discomfort and can give an unpleasant feeling. Taking a sample from the back of the throat may cause the volunteer to gag. When the sample is taken from the back of the nose, the volunteer may experience a stinging sensation and the eyes may become watery.

Contacts

Public
Clexio Biosciences Ltd

Haftzadi St. 21
Jerusalem 9548402
IL
Scientific
Clexio Biosciences Ltd

Haftzadi St. 21
Jerusalem 9548402
IL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Sex : male or female; females must be of nonchildbearing potential or postmenopausal.
2. Age : 40 to 80 years, inclusive, at screening.
3. Body mass index (BMI) : 18.0 to 32.0 kg/m2, inclusive, at screening.
4. Weight : >=50 kg, at screening.
5. Status : PD patients (diagnosed according to UK PD Society Brain Bank Criteria).

Further criteria apply

Exclusion criteria

1. Previous participation in the current study.
2. Employee of ICON or the Sponsor.
3. History of alcohol abuse or drug addiction within the last year (including soft drugs like cannabis products), except for tobacco use disorder.
4. Positive drug and alcohol screen (opiates, methadone, cocaine, amphetamines [including ecstasy], cannabinoids, barbiturates, benzodiazepines, and alcohol) at screening or admission (Day 1 for Part A and Day -1 for Part B) to the clinical research center. For cannabinoids, in case of a positive screen the Investigator should decide whether this is related to medical or recreational use (then subject may be included) or to drug addiction (then subject should be excluded).
5. Average intake of more than 24 units of alcohol per week (1 unit of alcohol equals approximately 250 mL of beer, 100 mL of wine, or 35 mL of spirits).

Further criteria apply

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):	28-03-2023
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	10-11-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-01-2023
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-09-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	13-09-2023
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	EUCTR2022-001855-17-NL
CCMO	NL82986.056.22