ISRCTN14216648 https://doi.org/10.1186/ISRCTN14216648

A study in patients with Parkinson's disease to evaluate a novel delayed-release, dual-pulse carbidopa and levodopa tablet, CP-012

Submission date
23/10/2024

Recruitment status
No longer recruiting

Registration date
23/10/2024

Overall study status
Deferred

Last Edited
07/07/2026

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Parkinson's disease is a disorder which affects the brain and results in symptoms such as muscle stiffness, resting tremor, slow movements and problems with balance or coordination. These symptoms can be particularly bad in the morning, when patients wake up as their evening dose of medication has worn off. This feeling of being unable to move freely in the morning is called "morning akinesia". Patients with Parkinson's also commonly have problems with sleeping as the effect of their medication wears off during the night. This presents as being immobile and unable to turn over overnight and is called "nocturnal immobility".

Carbidopa and levodopa are existing treatments for Parkinson's and are available as several marketed combination tablets, e.g. Sinemet. The currently marketed tablet formulations are not specifically designed to have an effect on overnight immobility symptoms or morning akinesia.

Contera Pharma, in collaboration with BDD Pharma, have developed a delayed-release tablet containing carbidopa and levodopa (CP-012). Two formulations of this tablet (CP-012A and CP-012B) have been designed to be taken at bedtime and release a pulse of carbidopa during the night, approximately 4 or 6 hours after taking the tablet. This is followed by a second delayed release of levodopa 30 to 60 minutes later, with the objective of achieving effective levels of these medications in the body overnight and on waking, and thus reducing the symptoms of morning akinesia and improving sleep quality.

Who can participate?
Parkinson's disease patients aged between 40 and 80 years, inclusive.

What does the study involve?
This is a single-centre, phase Ib, three-armed, open-label, cross-over, overnight pharmacoscintigraphic study in patients with Parkinson's.

For each participant, the study will consist of a pre-screening visit, a screening visit, 3 treatment visits and a follow-up visit.

Participants will receive one of the following treatments at each of the three Treatment Visits:

Treatment A: One 4hr delayed release Oralogik™ tablet (CP-012A)

Treatment B: One 6hr delayed release Oralogik™ tablet (CP-012B)

Treatment C: One tablet of Sinemet PLUS 25 mg/100 mg

The order in which participants receive the treatments will be randomly allocated.

To monitor how the new formulations behave in the gastrointestinal tract after being administered, a small amount of radiation will be added to Treatments A and B. The radiation emitted will be detected by taking images using a gamma camera. Blood samples will be taken at all treatment visits to assess the amount of medication absorbed into the body/bloodstream.

What are the possible benefits and risks of participating?
Participants may notice an improvement in their overnight or early morning movement-related symptoms after taking one of these study medications. If this occurs, this will only last for that one visit and will not persist after their involvement in the study has finished.

The results obtained from this study could be important for the further development of these formulations, which may, in future, be available to help patients with symptoms of nocturnal sleep disturbance and morning akinesia.

Participants will receive a small exposure to radiation. The radiation dose is low and similar to that used in routine medical imaging procedures.

Where is the study run from?
BDD Pharma

When is the study starting and how long is it expected to run for?
October 2024 until July 2025.

Who is funding the study?
Contera Pharma

Who is the main contact?
Dr Lyn Corry, Lyn.Corry@bddpharma.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1010244

Protocol serial number
BDD22306b

Study information

Scientific Title
A pharmacoscintigraphic single-centre, open-label, randomised, 3-way cross-over study in patients with Parkinson's to evaluate a novel delayed release, dual pulse carbidopa and levodopa tablet, CP-012

Study objectives
Primary objective
To evaluate the pharmacokinetics of levodopa and carbidopa from the delayed release tablets (CP-012) and correlate with scintigraphic time and site of release in patients with Parkinson's.

Secondary objectives
To compare the pharmacokinetics of the levodopa and carbidopa time delayed tablets (CP-012) with an immediate release product (Sinemet IR) in patients with Parkinson's.
To determine the gastrointestinal transit parameters of CP-012 in patients with Parkinson's.
To evaluate the safety and tolerability of CP–012 in patients with Parkinson's.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/08/2024, London - Surrey Borders Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 2071048057; surreyborders.rec@hra.nhs.uk), ref: 24/LO/0438

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking

Blinded (masking used)

Control
Active

Assignment
Crossover

Purpose
Treatment

Study type(s)
Other

Health condition(s) or problem(s) studied
Parkinson’s disease

Interventions
Current interventions as of 07/07/2026:
Pharmacoscintigraphic open-label crossover study. Participants were randomised to the sequence of treatment administration according to the randomisation schedule provided by the Sponsor.

Treatment A: One 4-hour delayed-release Oralogik™ tablet (CP-012A).

Treatment B: One 6-hour delayed-release Oralogik™ tablet (CP-012B).

Treatment C: One tablet of Sinemet PLUS 25 mg/100 mg.

Previous interventions:
Pharmacoscintigraphic open-label crossover study

Treatment A: One 4-hour delayed-release Oralogik™ tablet (CP-012A).

Treatment B: One 6-hour delayed-release Oralogik™ tablet (CP-012B).

Treatment C: One tablet of Sinemet PLUS 25 mg/100 mg.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
CP-012A, CP-120B

Primary outcome(s)

1. Time and location of onset and complete release of the radiolabelled tablet core of the CP-12 tablets, measured using scintigraphic imaging at 0 (pre-dose), 1, 2, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10, 12, 14 and 16 hours post-dose, for Treatment A and B, and 0 (pre-dose), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10, 12, 14 and 16 hours post-dose for Treatment C

2. Pharmacokinetic parameters of levodopa and carbidopa from the CP-012 formulations measured using samples collected for bioanalysis at 0 (pre-dose), 1, 2, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10, 12, 14 and 16 hours post-dose, for Treatment A and B, and 0 (pre-dose), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10, 12, 14 and 16 hours post-dose for Treatment C

Previous primary outcome timepoints as of 07/07/2026:
pre-determined timepoints up to 16 hours post-dose

Key secondary outcome(s)
1. Pharmacokinetic parameters of levodopa and carbidopa following single dose administration of CP-012 and Sinemet IR measured using samples collected for bioanalysis at 0 (pre-dose), 1, 2, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10, 12, 14 and 16 hours post-dose, for Treatment A and B, and 0 (pre-dose), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10, 12, 14 and 16 hours post-dose for Treatment C

2. Gastrointestinal transit parameters (gastric emptying time, small intestinal transit time and colonic arrival time (where applicable)) of the CP-012 tablets measured using scintigraphic imaging at 0 (pre-dose), 1, 2, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 10, 12, 14 and 16 hours post-dose, for Treatment A and B, and 0 (pre-dose), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10, 12, 14 and 16 hours post-dose for Treatment C

3. Safety and tolerability of single dose administration of CP-012 and Sinemet IR measured using the number of treatment-emergent adverse events at the end of the study

Previous key secondary outcome timepoints as of 07/07/2026:
pre-determined timepoints up to 16 hours post-dose

Completion date
14/07/2025

Eligibility

Key inclusion criteria
1. Informed consent obtained prior to any trial-related activities
2. Female or male patients with a diagnosis of established Parkinson’s as per the Movement Disorder Society (MDS) Criteria and previously confirmed by a Neurologist
3. On therapy with levodopa for ≥ 3 years and currently receiving ≥ 3 daily doses
4. Participants should experience motor fluctuations induced by levodopa regularly, as per the judgement of the investigator
5. Participants must be 40-80 years of age (both inclusive) at the time of signing the informed consent
6. A female participant is eligible to participate if she is not pregnant or breastfeeding, and one of the following conditions applies:
6.1. Is a woman of nonchildbearing potential (WONCBP)
OR
6.2. Is a WOCBP and using a contraceptive method that is highly effective (with a failure rate of <

1% per year), with low user dependency. Contraceptive and Barrier Guidance during the study intervention period and until the final follow-up visit, and agrees not to donate eggs (ova, oocytes) for the purpose of reproduction during this period.
7. Male participants are eligible to participate if they agree to the following during the study intervention period and for a period of 3 months after the last treatment visit:
7.1. Refrain from donating sperm
PLUS, either:
7.2. Be “True abstinent”, i.e., abstinent from heterosexual intercourse as their preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent
OR
7.3. Must agree to use contraception /barrier as detailed below
7.4. Agree to use a male condom with a female partner, use of an additional highly effective contraceptive method with a failure rate of < 1% per year as described in Appendix 4 Contraceptive and Barrier Requirements
7.5. Surgically sterilized
8. BMI between 18 and 35 kg/m², inclusive
9. Functionally able and sufficiently independently mobile to comply with protocol procedures and overnight stays at the clinic
10. Willing and able to eat the standardised meals as per study-specific meal plan

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Regular levodopa regimen includes dosing after 11 pm to control nighttime problems
2. Expected to not tolerate changes in their evening antiparkinsonian schedule required by the study protocol
3. Expected not to tolerate being “OFF” during the night, which would require extra intake of levodopa during the night, after study drug administration
4. Current or recurrent disease that could affect study conduct; safety of the patients; ability of the patient to complete the study in the opinion of the investigator
5. Current or relevant previous history of serious, severe or unstable psychiatric illness, including Parkinson’s Disease, Dementia or drug-induced psychosis, as per judgement of the Investigator

or based on a MMSE score <25, HAM-D score of greater than 18
6. Patients with disabling dyskinesia that could interfere with their ability to complete study procedures at the Investigator's judgement
7. Participants at high risk of falls as judged by the Investigator
8. A positive urine drug screen for drug abuse, a positive alcohol test, a history of substance abuse, including alcohol abuse (as judged by the investigator), or unwillingness to refrain from consuming alcohol for 24 hours prior to each treatment visit and when on site
9. A positive pregnancy test result for women of childbearing potential
10. Participation in another clinical study (inclusive of the final post-study examination) of an investigational drug within the 12 weeks before screening visit, or five elimination half-lives of the previous study drug, whichever is longer
11. Known hypersensitivity to IMP or similar compound or to excipients contained in the IMP formulation
12. Receiving Parkinson’s infusion therapies or DBS therapy within 12 weeks prior to screening
13. Patients with frequent use of overnight rescue medication, which could interfere with the treatment regime and measurement for the trial, as per the judgement of the investigator
14. Participant is scheduled to take prescribed medication within 14 days prior (or 5 half lives – whichever is longer) or takes over-the-counter medication within 48 hours prior to the first dose or any subsequent treatment visit which, in the opinion of the PI or medically qualified designee responsible, will interfere with the study procedures (or has the potential to affect gastric emptying and/or gut transit) or compromise safety of the patient. This includes, but is not exclusive to:
14.1. Oral preparations of iron
14.2. Antidiarrhoeals such as loperamide
14.3. Pro-kinetics such as domperidone, prucalopride or metoclopramide
14.4. Antispasmodics such as Buscopan
14.5. “natural levodopa” formulations such as mucuna pruriens
14.6. Non-selective monoamine oxidase (mao) inhibitors
14.7. Dopamine D2 receptor antagonists (e.g., risperidone, phenothiazines)
14.8. Tricyclic antidepressants
14.9. Anticholinergics
14.10. Dopamine depleting agents (e.g., tetrabenazine)
14.11. Isoniazid
14.12. Phenytoin
15. Participant has a total dosimetry value which, in the opinion of the PI or medically qualified designee/physician responsible, contraindicates their participation
16. Blood donation or significant blood loss within 3 months of screening and for the duration of the study
17. Participant has any non-removable metal objects such as metal plates, screws, etc., in their chest or abdominal area, which, in the opinion of the PI or medically qualified designee, could affect the study conduct
18. Any clinically significant findings in screening assessment, including ECG, and safety laboratory measurements
19. Temperature > 38° Celsius at pre-screening or screening visit

Date of first enrolment
23/10/2024

Date of final enrolment
10/06/2025

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Glasgow Royal Infirmary
84 Castle Street
Glasgow
Scotland
G4 0SF

Sponsor information

Organisation
Contera Pharma

Funder(s)

Funder type
Industry

Funder Name
Contera Pharma

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results			26/06/2026	No	No