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A five-part drug-drug interaction study of REN001 in healthy volunteers

Submission date
24/10/2022

Recruitment status
No longer recruiting

Registration date
25/11/2022

Overall study status
Completed

Last Edited
28/02/2024

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of this study is to evaluate the study drug REN001 in the context of a multi-part drug-drug interaction (DDI) study. The overall objectives of the study are to determine the safety, tolerability (the degree to which the side effects of a drug can be tolerated) and potential for effects known as drug-drug interactions when the study drug is evaluated in different conditions (i.e., different dose strengths and when administered alone and in combination with five different types of drugs). The study will also evaluate the levels of two metabolite (breakdown) products of REN001 in the blood.

Who can participate?
A total of up to 82 participants are needed to fully complete this study. Participants must be healthy adult males and females aged between 18 and 60 years.

What does the study involve?
The study will be split into up to five parts as follows:

Part A – REN001 & Gemfibrozil - enrolling up to 14 healthy males and females (of childbearing and non-childbearing potential), evaluating the drug-drug interaction potential of REN001 following the co-administration of gemfibrozil. In this part of the study, gemfibrozil (a known Cytochrome P450 3A (CYP2C8) enzyme inhibitor) will be co-administered with REN001 to determine if there is any effect or interaction between the two drugs in the body and whether administration of gemfibrozil affects the safety, tolerability and pharmacokinetics of REN001 and its metabolites. The purpose of this is to understand how co-administration of medications with known enzyme inhibition may affect and interact with the metabolism of REN001. Part A of the study will consist of a screening visit (between 35 and 1 day prior to the first dose), one treatment period consisting of an overall period of 34 days, split into 4 main in-house periods (Days -1-3, Days 6-9, Days 15-18, and Days 21-26) and a post-study follow-up visit 5-7 days after the last dose of gemfibrozil on Day 32.

Part B – REN001 & Fluconazole - enrolling up to 14 healthy males and females (of childbearing and non-childbearing potential), evaluating the drug-drug interaction potential of REN001 following the co-administration of fluconazole. In this part of the study, fluconazole (a known

Cytochrome P450 3A (CYP3A) & CYP2C9 enzyme inhibitor) will be co-administered with REN001 to determine if there is any effect or interaction between the two drugs in the body and whether administration of fluconazole affects the safety, tolerability and pharmacokinetics of REN001 and its metabolites. The purpose of this is to understand how co-administration of medications with known enzyme inhibition may affect and interact with the metabolism of REN001. Part B of the study will consist of a screening visit (between 35 and 1 day prior to the first dose), one treatment period consisting of an overall period of 19 days, split into two main in-house periods (Days -1-3 and Days 6-11) and a post-study follow-up visit 5-7 days after the last dose of fluconazole on Day 17.

Part C – REN001 & Fexofenadine - enrolling up to 24 healthy males and females (of childbearing and non-childbearing potential), evaluating the drug-drug interaction potential of REN001 following the co-administration of fexofenadine. In this part of the study, fexofenadine (a known P-gp & OATP1B substrate) will be co-administered with REN001 to determine if there is any effect or interaction between the two drugs in the body and whether administration of REN001 affects the safety, tolerability and pharmacokinetics of fexofenadine. The purpose of this is to understand how co-administration of medications with known transporter pathways may affect and interact with the metabolism of REN001. Part C of the study will consist of a screening visit (between 35 and 1 day prior to the first dose), one treatment period consisting of an overall period of 17 days, split into two main in-house periods (Days -1-3 and Days 11-14) and a post-study follow-up visit 5-7 days after the last dose of REN001 on Day 15.

Part D – REN001 & Rosuvastatin - enrolling up to 16 healthy males and females (of childbearing and non-childbearing potential), evaluating the drug-drug interaction potential of REN001 following the co-administration of rosuvastatin. In this part of the study, rosuvastatin (a known OATP1B & BCRP substrate) will be co-administered with REN001 to determine if there is any effect or interaction between the two drugs in the body and whether administration of REN001 affects the safety, tolerability and pharmacokinetics of rosuvastatin. The purpose of this is to understand how co-administration of medications with known transporter pathways may affect and interact with the metabolism of REN001. Part D of the study will consist of a screening visit (between 35 and 1 day prior to the first dose), one treatment period consisting of an overall period of 17 days, split into two main in-house periods (Days -1-3 and Days 11-14) and a post-study follow-up visit 5-7 days after the last dose of REN001 on Day 15.

Part E (Optional) – REN001 & Carbamazepine - enrolling up to 14 healthy males and females (of childbearing and non-childbearing potential), evaluating the drug-drug interaction potential of REN001 following the co-administration of carbamazepine. In this part of the study, carbamazepine (a known Cytochrome P450 3A (CYP3A) & CYP2C9 enzyme inducer) will be co-administered with REN001 to determine if there is any effect or interaction between the two drugs in the body and whether administration of carbamazepine affects the safety, tolerability and pharmacokinetics of REN001 and its metabolites. The purpose of this is to understand how co-administration of medications with known enzyme induction may affect and interact with the metabolism of REN001. Part E of the study will consist of a screening visit (between 35 and 1 day prior to the first dose), one treatment period consisting of an overall period of 26 days, split into two main in-house periods (Days -1-3 and Days 20-23) and a post-study follow-up visit 5-7 days after the last dose of carbamazepine on Day 24.

What are the possible benefits and risks of participating?
Taking part in this study is not expected to provide participants with any direct medical benefit. However, the information from this study may help improve the treatment of diseases associated with dysfunction in the process of metabolism and cellular energy production.
Full information on possible side effects/risks is provided to volunteers in the Participant

Information Sheet and Informed Consent Form.
Throughout the study the health of the participants will be regularly monitored and appropriate treatment for any medical condition will be provided if required. All doctors employed by Simbec-Orion are trained and certified in Advanced Life Support Procedures in order to deal with a medical emergency. Nurses and other clinical staff are also trained in emergency procedures. Simbec-Orion also has an agreement with Prince Charles Hospital for the referral of participants if required following a medical emergency.

Where is the study run from?
Simbec-Orion Clinical Pharmacology Unit (UK)

When is the study starting and how long is it expected to run for?
July 2022 to March 2023

Who is funding the study?
Reneo Pharma Ltd (UK)

Who is the main contact?
general.ethics.correspondence@simbecorion.com

Study website
Not applicable

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
2022-002224-13

IRAS number
1006047

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
REN001-106, IRAS 1006047

Study information

Scientific Title
A five-part, Phase I, open-label, drug-drug interaction study examining the effect of gemfibrozil, fluconazole and carbamazepine on the safety, tolerability and pharmacokinetics of REN001, and the effect of REN001 on the safety, tolerability and pharmacokinetics of fexofenadine and rosuvastatin in healthy subjects

Study objectives
The primary objectives of this study are:

Part A:
1. To assess the effect of the index strong CYP2C8 inhibitor, gemfibrozil, on the PK of REN001 and its two metabolites, in healthy subjects.

Part B:
2. To assess the effect of the index moderate CYP3A/CYP2C9 inhibitor, fluconazole, on the PK of REN001 and its two metabolites, in healthy subjects.

Part C:
3. To assess the effect of REN001 on the PK of the known P-glycoprotein (P-gp) and Organic anion transporting polypeptide 1B (OATP1B) substrate, fexofenadine, in healthy subjects.

Part D:
4. To assess the effect of REN001 on the PK of the known Breast Cancer Resistance Protein (BCRP) and OATP1B substrate, rosuvastatin, in healthy subjects.

Part E (Optional):
5. To assess the effect of the known CYP3A/CYP2C9 inducer, carbamazepine, on the PK of REN001 and its two metabolites; M351 and M527, in healthy subjects.

The secondary objectives of this study are:
1. To assess the safety and tolerability of REN001 and the respective NIMP; gemfibrozil (Part A), fluconazole (Part B), fexofenadine (Part C) and rosuvastatin (Part D), carbamazepine (Part E; Optional), when administered concomitantly.
2. To assess the intra-subject plasma PK variability of single doses of REN001 when administered on two separate occasions 7 days apart (Part A).
3. To assess the effect of REN001 on the disposition of an endogenous OATP1B biomarker, Coproporphyrin I (Part A).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/08/2022, Wales Research Ethics Committee 1 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road, East Cardiff, CF11 9AB, UK; +44 (0)2920 230457; Wales.REC1@wales.nhs.uk), ref: 22/WA/0226

Approved 30/08/2022, MHRA (10 South Colonnade, Canary Wharf, London E14 4PU; +44 (0) 20 3080 6000; info@mhra.gov.uk), ref: CTA 49733/0006/001-0001

The HRA has approved deferral of publication of trial details.

Study design
A five-part drug-drug interaction trial in up to 82 healthy volunteers

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Pharmaceutical testing facility, Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
The study incorporated five drug-drug interaction (DDI) investigations with REN001 and five different NIMPs as follows; gemfibrozil (Part A), fluconazole (Part B), fexofenadine (Part C),

rosuvastatin (Part D) and carbamazepine (Part E; optional). Part A, Part B and Part E enrolled single cohorts containing up to 14 subjects each, Part C enrolled two cohorts containing up to 24 subjects, and Part D enrolled a single cohort containing up to 16 subjects.

The study took place in the Clinical Pharmacology Unit of Simbec-Orion Clinical Pharmacology under medical and nursing supervision. From the screening to post-study follow-up the duration for participation was as follows:
Part A – 10 weeks
Part B, C & D – 8 weeks
Part E – 9 weeks

Screening (All Study Parts; Day -35 to Day -1)
Screening assessments were performed from Day -35 to Day -1 to ensure the eligibility of subjects.

Part A (REN001 and gemfibrozil)
Day -1 to Day 5
Subjects entered the Clinical Pharmacology Unit on Day -1 to complete confirmation of eligibility and baseline assessments. On Day 1 a single 100 mg dose of REN001 was administered 30 mins following the start of a standardised meal. Subjects remained in-house until after the 48-hour assessments were completed on Day 3 after which they returned on Day 4 and Day 5 for single-day visits to complete the required assessments.

Day 6 to Day 14
Subjects completed another in-house period at the Clinical Pharmacology Unit from Day 6 until Day 9. On Day 7 a single 100 mg dose of REN001 was administered 30 mins following the start of a standardised meal. Subjects remained in-house until Day 9 before returning on Day 10 and Day 11 for single-day visits to complete the required assessments. While subjects were not required to visit the Clinical Pharmacology Unit on Days 12 – 14, they received a phone call from an Investigator (or delegate).

Day 15 to Day 20
Subjects entered the Clinical Pharmacology Unit on Day 15 to start another in-house period. On Day 16 a single 25 mg dose of REN001 was administered 30 mins following the start of a standardised meal. Subjects remained in-house until Day 18 before returning on Day 19 and Day 20 for single-day visits to complete the required assessments.

Day 21 to Day 33
Subjects completed another in-house period at the Clinical Pharmacology Unit from Day 21 to Day 26. From Day 22 to Day 32 they were administered 600 mg of gemfibrozil twice daily, 30 min before starting a standard meal. On Day 23 they received a single 25 mg dose of REN001 (administered approximately 1 h following the first Day 23 dose of gemfibrozil, and 30 mins following the start of a standardised meal). Subjects returned on each day from Day 27 to Day 33.

Part B (REN001 and fluconazole)
Day -1 to Day 5
Subjects entered the Clinical Pharmacology Unit on Day -1 to complete confirmation of eligibility and baseline assessments. On Day 1 a single 25 mg dose of REN001 was administered 30 mins following the start of a standardised meal. Subjects remained in-house until Day 3 before returning on Day 4 and Day 5 for single-day visits to complete the required assessments.

Day 6 to Day 18
Subjects completed another in-house period at the Clinical Pharmacology Unit from Day 6 to Day 11. On Day 7 they received a single 400 mg dose of fluconazole 30 mins following the start of a standardised meal, and from Day 8 to Day 17 subjects received a single daily 200 mg dose of fluconazole, all dosed 30 mins following the start of a standard meal. On Day 8 they received a single 25 mg dose of REN001 (administered with the dose of fluconazole, and 30 mins following the start of a standardised meal). Subjects returned on each day from Day 12 to Day 18 to receive their doses of fluconazole and complete the required assessments.

Part C (REN001 and fexofenadine)
Day -1 to Day 5
Subjects entered the Clinical Pharmacology Unit on Day -1 to complete confirmation of eligibility and baseline assessments. On Day 1 a single 60 mg dose of fexofenadine was administered at least 1 h before a standardised meal. Subjects remained in-house until Day 3 and they returned on Day 4 and Day 5 for single-day visits to complete the required assessments.

Day 6 to Day 16
From Day 6 to Day 15, subjects took a 100 mg dose of REN001 once daily 30 mins following the start of a standardised meal, with the exception of Day 12. Days 6 to 10 were single-day visits, followed by an in-house period from Day 11 to Day 14. On Day 12, subjects received a single 60 mg dose of fexofenadine and a 100 mg dose of REN001, both administered at least 1 h before a standardised meal. Subjects returned for single-day visits on Day 15 and Day 16 to receive their doses of REN001 and complete the required assessments.

Part D (REN001 and rosuvastatin)
Day -1 to Day 5
Subjects entered the Clinical Pharmacology Unit on Day -1 to complete confirmation of eligibility and baseline assessments. On Day 1 a single 10 mg dose of rosuvastatin was administered 30 mins following the start of a standardised meal. Subjects remained in-house until Day 3 and returned on Day 4 and Day 5 for single-day visits to complete the required assessments.

Day 6 to Day 16
From Day 6 to Day 15, subjects took a 100 mg dose of REN001 once daily 30 min following the start of a standardised meal. Days 6 to 10 were single-day visits, followed by an in-house period from Day 11 to Day 14. On Day 12, subjects received a single 10 mg dose of rosuvastatin (administered with the dose of REN001, and 30 mins following the start of a standardised meal). Subjects returned for single-day visits on Day 15 and Day 16 to receive their final doses of REN001 and complete the required assessments.

Part E (REN001 and carbamazepine; Optional)
Day -1 to Day 6
Subjects entered the Clinical Pharmacology Unit on Day -1 to complete confirmation of eligibility and baseline assessments. Subjects completed an in-house period at the Clinical Pharmacology Unit from Day -1 until Day 3. On Day 1 a single 100 mg dose of REN001 was administered 30 mins following the start of a standardised meal. Subjects remained in-house until Day 3 and returned on Day 4 and Day 5 for single-day visits to complete the required assessments. While subjects were not required to visit the Clinical Pharmacology Unit on Day 6, they received a phone call from an investigator (or delegate).

Day 7 to Day 19
Subjects returned to the Clinical Pharmacology Unit on each day from Day 7 to Day 19 in order to receive the twice-daily doses of carbamazepine administered 30 minutes after commencing a

standard meal. The dose strength and frequencies were as follows; 100 mg BID for Day 7 to Day 9, 200 mg BID for Day 10 to Day 12, and 300 mg BID for Day 13 to Day 19.

Day 20 to Day 25
Subjects continued to receive 300 mg of carbamazepine twice daily from Day 20 to Day 24. They completed an in-house period at the Clinical Pharmacology Unit from Day 20 to Day 23. On Day 21, subjects were administered a single 100 mg dose of REN001 in addition to 300 mg of carbamazepine BID (REN001 administered with the first Day 21 dose of carbamazepine, 30 mins following the start of a standardised meal). Subjects returned on Day 24 and Day 25 for single-day visits to complete the required assessments.

Post-Study (All Study Parts)
A post-study follow-up visit was conducted 5 – 7 days post final dose of IMP/NIMP.

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Drug Drug Interaction

Phase
Phase I

Drug/device/biological/vaccine name(s)
Mavodelpar (REN001)

Primary outcome measure
Pharmacokinetic (PK) parameters derived from analysis of plasma samples for concentrations of REN001 and its metabolites (M351 and M527) in Parts A, B & E, fexofenadine in Part C and rosuvastatin in Part D:
1. Cmax - Maximum plasma concentration
2. Tmax - Time of Cmax
3. t½ - Terminal elimination half-life
4. AUC0-t - Area under the plasma concentration-time profile from time zero to the time of the last measurable concentration (Clast)
5. AUCinf - Area under the plasma concentration-time profile from time zero extrapolated to infinite time
6. AUC0-t metabolite to parent ratios (REN001 only) - AUC0-t (metabolite) / AUC0-t (REN001)
7. AUCinf metabolite to parent ratios (REN001 only) - AUCinf (metabolite) / AUCinf (REN001)
In addition, λz, CL/F, Vz/F, AUC%extrapolated will be derived and reported for REN001 (and its metabolites) fexofenadine and rosuvastatin.

Blood samples for PK analysis were taken at the following timepoints:
Part A: 71 timepoints from Day 1 pre-dose to Day 33
Part B: 37 timepoints from Day 1 pre-dose to Day 18
Part C/D: 36 timepoints from Day 1 pre-dose to Day 16
Part E: 34 timepoints from Day 1 pre-dose to Day 25

Secondary outcome measures
1. Safety endpoints defined as follows:
1.1. Adverse events (AEs) recorded from the point of informed consent up to the final post-

study follow-up visit in each part
1.2. Laboratory safety (biochemistry, haematology, coagulation and urinalysis)
1.3. Vital signs (systolic/diastolic blood pressure, pulse, oral body temperature and respiratory rate)
1.4. 12-lead ECG (heart rate, PR interval, QRS width, QT interval and QTcF interval)
Safety endpoints will be evaluated at set points within the following periods:
Part A: screening to post-study follow-up (up to Day 39)
Part B: screening to post-study follow-up (up to Day 24)
Part C/D: screening to post-study follow-up (up to Day 22)
Part E: screening to post-study follow-up (up to Day 31)
2. Pharmacokinetic parameters derived from analysis of plasma samples for concentrations of Coproporphyrin I (for Part A only):
2.1. Cmax - Maximum plasma concentration
2.2. Tmax - Time of Cmax
2.3. AUC0-24 - Area under the plasma concentration-time profile from time zero to 24 hours post-dose
Blood samples for PK analysis of secondary endpoints were taken at the following timepoints:
Part A: 13 timepoints from Day 1 pre-dose to 24 hours post-dose

Overall study start date
19/07/2022

Completion date
14/03/2023

Eligibility

Key inclusion criteria
1. Healthy male and female subjects, between 18 and 60 years of age, inclusive.
2. Female subject with a negative pregnancy test at Screening.
3. Subjects must agree to adhere to the contraception requirements defined in the study protocol.
4. Subject with a body mass index (BMI) of 18-32 kg/m2 (BMI = body weight (kg) / [height (m)]2)
5. No clinically significant history of previous allergy/sensitivity to REN001, gemfibrozil, fluconazole, fexofenadine, rosuvastatin, carbamazepine or any of the excipients contained within the IMP/NIMPs.
6. No clinically significant abnormal test results for serum biochemistry, haematology, coagulation and/or urine analyses within 35 days before the first dose administration of the IMP /NIMP.
7. Subject with a negative urinary drugs of abuse (DOA) screen (including alcohol) test results, determined within 35 days before the first dose administration of the IMP/NIMP (N.B.: A positive test result may be repeated at the Investigator’s discretion).
8. Subject with negative human immunodeficiency virus (HIV), hepatitis B surface antigen (HBsAg)) and hepatitis C virus antibody (HCV Ab) test results at Screening.
9. No clinically significant abnormalities in 12-lead electrocardiogram (ECG) determined within 35 days before first dose of IMP/NIMP including a PR interval >220 ms, QT interval heart rate corrected using Fridericia’s formula QTcF >450 ms.
10. No clinically significant abnormalities in vital signs (e.g., blood pressure, pulse, respiratory rate and oral temperature) determined within 35 days before first dose of IMP/NIMP.

11. Subject must be available to complete the study (including all follow-up visits).
12. Subject must satisfy an Investigator about his/her fitness to participate in the study.
13. Subject must provide written informed consent to participate in the study.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
82

Total final enrolment
83

Key exclusion criteria
1. A clinically significant history of gastrointestinal disorder likely to influence IMP/NIMP administration and absorption.
2. Use of prescription or non-prescription drugs, including vitamins, herbal and dietary supplements within 35 days or 5 half-lives (whichever is longer) prior to the first dose of IMP /NIMP with the exception of paracetamol (which may be taken as an analgesic to a maximum of 2 g in 24 h) and ibuprofen (which may be taken as an analgesic to a maximum of 1.2 g in 24 h [400 mg 3 times a day]).
3. Subjects who have previously received REN001.
4. Evidence of renal, hepatic, central nervous system, respiratory, cardiovascular or metabolic dysfunction.
5. Suitable veins for venepuncture and cannulation.
6. Presence or history of clinically significant allergy requiring treatment, as judged by the Investigator. Hay Fever is allowed unless active.
7. A clinically significant history of drug or alcohol abuse (defined as the consumption of more than 14 units [for male and female subjects] of alcohol a week) within the past two years.
8. Medical history that would preclude the administration of the NIMPs.
9. Inability to communicate well with the Investigators (i.e., language problem, poor mental development or impaired cerebral function).
10. Participation in a New Chemical Entity (NCE) clinical study within the previous 3 months or five half-lives, whichever is longer, or a marketed drug clinical study within 30 days or five half-lives, whichever is longer, before the first dose of IMP/NIMP. (The washout period between studies is defined as the period of time elapsed between the last dose of the previous study and the first dose of the next study).
11. Donation or loss of 450 mL or more blood within the 3 months before the first dose of IMP /NIMP or no plans to donate blood in the 3 months following completion of the study.

12. Vegans, vegetarians or other dietary restrictions (e.g., restrictions for medical, religious or cultural reasons, etc) that would prevent the subject from consuming a standardised meal or gelatine capsule.
13. Willing and able to swallow gelatin capsules.
14. Users of nicotine products i.e., current smokers or ex-smokers who have smoked within the 6 months prior to Screening or users of cigarette replacements (i.e., e-cigarettes, nicotine patches or gums).
15. Female subjects who are pregnant, breastfeeding or lactating.
16. Subjects who have received a COVID-19 vaccine injection within 35 days prior to the first dose of IMP/NIMP.

Date of first enrolment
16/09/2022

Date of final enrolment
13/02/2023

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Simbec-Orion Clinical Pharmacology (AKA Simbec Research Ltd)
Simbec-Orion Clinical Pharmacology
Merthyr Tydfil Industrial Park
Cardiff Road
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United Kingdom
CF48 4DR

Sponsor information

Organisation
Reneo Pharma Ltd (United Kingdom)

Sponsor details
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Sponsor type
Industry

Website
https://reneopharma.com/

Funder(s)

Funder type
Industry

Funder Name
Reneo Pharma Ltd (United Kingdom)

Results and Publications

Publication and dissemination plan
In accordance with the approved HRA deferral, full trial details have now been published in the registry. There are no plans to publish in a peer-reviewed journal.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non-therapeutic clinical trials.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No