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A study in healthy volunteers to assess how the test medicine (IB1001) affects how the body takes up Digoxin and Rosuvastatin (Part 1) and how food affects blood levels of IB1001 (Part 2)

Submission date
29/03/2025

Recruitment status
No longer recruiting

Registration date
15/05/2025

Overall study status
Ongoing

Last Edited
15/05/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
The Sponsor is developing the test medicine, IB1001, as a potential treatment for rare neurological (brain and nerve) disorders, including Niemann-Pick disease type C (NPC), GM2 gangliosidosis, and ataxia telangiectasia (AT).
In this study in healthy volunteers, the aim is to answer these questions:
1. Does taking the test medicine with Digoxin and Rosuvastatin affect the blood levels of the approved medicines?
2. Does food affect how the test medicine gets into the bloodstream?
This study will also provide more information on the safety and tolerability of the test medicine, and any side effects.

Who can participate?
Healthy men and non-pregnant non-lactating women aged 18 to 55 years

What does the study involve?
In Part 1, participants will receive a single oral dose of digoxin and rosuvastatin, followed by a 5-day washout period. Volunteers will then receive a single dose of digoxin and rosuvastatin followed by a 3-times daily oral dose of IB1001 for 5 days. They'll stay in the clinic for 12 nights, attend 1 outpatient visit, and take up to 7 weeks to finish the study.
In Part 2, participants will receive two single doses of IB1001; once in a fed and once in a fasted state. The order in which state they will receive these doses is selected randomly. There will be a washout period of 24 hours between the doses. They'll stay in the clinic for 3 nights, attend 1 outpatient visit, and take up to 6 weeks to finish the study.
Samples will be collected to:
1. Do safety tests (blood and urine)
2. Measure the amount of the test medicine (blood; Parts 1 and 2) and amounts of digoxin and rosuvastatin (blood; Part 1 only)

What are the possible benefits and risks of participating?
Volunteers may experience side effects from the test medicine and the marketed medications. Full information on possible side effects is in the Participant Information Sheet and Informed Consent Forms. There is always a risk of unexpected side effects or an allergic reaction. To mitigate the risk, we'll ensure that volunteers meet the entry criteria for the study and monitor volunteers closely throughout the study.
Our screening tests might be of benefit if we find an important medical problem, but they might reveal something that the volunteer would prefer not to know about. If there are medically important findings in our tests at screening or during the study, we will inform the volunteer's GP.
Volunteers will be confined to the clinic during the study and must make outpatient visits and comply with the lifestyle restrictions described in the PIS-ICF, including periods of fasting from food and drink except water and short periods during which they will be allowed no fluids.
Due to the target indication of the test medicine, the study population includes women of childbearing potential. It is unknown whether the test medicine might harm unborn children, so all volunteers must follow the restrictions on donation of sperm or eggs and use acceptable contraception. Women of childbearing potential will be involved in this study, as long as they comply with the contraception requirements outlined in the protocol. If a volunteer or a partner of a volunteer becomes pregnant during the study, we would ask permission to follow up on the pregnancy.
Volunteers will undergo many tests and procedures during the study.
Blood sampling can cause soreness and bruising of the arms but these problems usually clear up within a few days to a few weeks. Susceptible volunteers may faint when we take blood samples; volunteers must lie down when we take blood samples to mitigate that risk.
ECG stickers may cause local skin irritation.
Sleep may be interrupted due to being housed on a ward with up to 19 other people.
Healthy volunteers will get no medical benefit from the test medicine; however, the aims of the study can be most efficiently met in volunteers with no concurrent medical conditions and who do not need to take concomitant medication that might interfere with the study objectives or increase the risk of the study. The risk/benefit evaluation in this study supports the use of healthy volunteers.
Volunteers will receive payment for participating in the study. There is always a risk that payment could represent coercion. However, payment will be based on committed time, inconvenience, and travel and other expenses, not on risk. An ethics committee will review the payment to ensure that it is fair.

Where is the study run from?
IntraBio Inc (USA)

When is the study starting and how long is it expected to run for?
March 2025 to November 2025

Who is funding the study?
IntraBio Inc (USA)

Who is the main contact?
recruitment@weneedyou.co.uk

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1011424

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS: 1011424, Study Code: IB1001-46839-46838, Quotient Code: QSC303160

Study information

Scientific Title

A two-part, open-label study designed to determine the pharmacokinetics of MDR1 and BCRP transporter probes (Digoxin and Rosuvastatin) alone and in combination with IB1001 in the fasted state, and to assess the effect of food on the pharmacokinetics of IB1001 in healthy subjects

Study objectives
This trial will meet the following primary and secondary objectives:

Primary Objectives:
1. To determine the effect of a single three times daily (TID) regimen of IB1001 on the single dose pharmacokinetics (PK) of digoxin (Part 1).
2. To determine the effect of a single TID regimen of IB1001 on the single dose PK of rosuvastatin (Part 1).
3. To determine the relative bioavailability of a single dose of IB1001 in the fasted vs fed state (Part 2).

Secondary Objectives:
1. To provide additional safety and tolerability information for a single TID regimen of IB1001 when co-administered with a single dose of digoxin (Part 1).
2. To provide additional safety and tolerability information for a single TID regimen of IB1001 when co-administered with a single dose of rosuvastatin (Part 1).
3. To provide additional safety and tolerability information for a single dose of IB1001 when administered in the fed and fasted state (Part 2).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/05/2025, Health and Social Care Research Ethics Committee B (HSC REC B) (Lissue Industrial Estate West, 5 Rathdown Walk, Lisburn, Co. Antrim, BT28 2RF, United Kingdom; -; recb@hscni.net), ref: 25/NI/0029

Study design
Two-part open-label part-randomized study

Primary study design
Interventional

Secondary study design
Part-randomized study

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Other, Safety

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

Health condition(s) or problem(s) studied
Niemann-Pick disease, GM2 gangliosidosis and ataxia telangiectasia

Interventions
This is a two-part study. Part 1 is a two-period, open-label, non-randomised study. Part 2 is an open-label, part-randomised, two-way crossover study. It is planned to enrol 16 and 14 healthy male and female volunteers in Parts 1 and 2, respectively. Participants will be admitted to the clinical unit on Day -1 of Period 1 in each study part. In Part 1, each participant will receive a single oral dose of 0.25 mg digoxin tablet and 10 mg rosuvastatin film-coated tablet on Day 1 of each study period. In Period 2, participants will receive three times daily doses of IB1001 Oral Suspension (levacetylleucine) on Days 1-5, to give a total daily dose of 4 g. All doses will be given in the fasted state, and there will be a washout period of 5 days between dosing in Periods 1 and 2. In Part 2, participants will be randomised to receive the test medicine in the fed and fasted states in Periods 1 and 2. In both study periods, participants will receive a single 2 g oral dose of IB1001 Oral Suspension on Day 1, following either a 10 h overnight fast or after consuming a high-fat breakfast. There will be a washout period of 24 h between Periods 1 and 2 in Part 2. Participants will be discharged from the clinical unit on Day 6 of Period 2 in Part 1, and on Day 2 of Period 2 in Part 2. In both study parts, participants will have a follow-up phone call between 3 and 7 days after their final dose in Period 2.

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Others (drug-drug interaction, food effect)

Phase
Phase I

Drug/device/biological/vaccine name(s)
IB1001 (INN: Levacetylleucine)

Primary outcome measure
Part 1:
1. PK parameters including but not limited to Cmax, AUC(0-last), and AUC(0-inf), for digoxin alone and in combination with IB1001, measured using blood samples taken from Period 1 Day 1 to Period 2 Day 6
2. PK parameters including but not limited to Cmax, AUC(0-last) and AUC(0-inf) for rosuvastatin alone and in combination with IB1001, measured using blood samples taken from Period 1 Day 1 to Period 2 Day 6

Part 2:
1. Results of the formal statistical analysis of PK parameters Cmax, AUC(0-last) and AUC(0 inf) for IB1001 in the fed vs fasted states, measured using blood samples taken from Period 1 Day 1 to Period 2 Day 2

Secondary outcome measures

Parts 1 and 2:
Safety and tolerability measured using the incidence of treatment-emergent adverse events, physical examinations and change from baseline in vital signs, electrocardiograms and laboratory safety tests from Day -1 of Period 1 until the follow-up phone call in each study part.

Overall study start date
26/03/2025

Completion date
27/11/2025

Eligibility

Key inclusion criteria
1. Must provide written informed consent
2. Must be willing and able to communicate and participate in the whole study
3. Subject is willing to consume the entirety of a high-fat breakfast including bacon, dairy and eggs (Part 2 only)
4. Aged 18 to 55 years inclusive at the time of signing informed consent
5. Must agree to adhere to the contraception requirements defined in the clinical protocol
6. Healthy male or non-pregnant, non-lactating healthy females according to the assessment of the investigator, as based on a complete medical history including a physical examination, vital signs, 12-lead ECG, and laboratory safety tests without any clinically significant abnormalities. Safety bloods, urinalysis, ECGs and vital signs to be re-checked at admission (Part 1 only)
7. Body mass index (BMI) of 18.0 to 32.0 kg/m2 as measured at screening
8. Weight ≥50 kg at screening

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Serious adverse reaction or serious hypersensitivity to any drug or formulation excipients
2. Presence or history of clinically significant allergy requiring treatment, as judged by the investigator. Hay fever is allowed unless it is active

3. History of clinically significant cardiovascular, renal, hepatic, dermatological, chronic respiratory or gastrointestinal disease, neurological or psychiatric disorder, as judged by the investigator
4. Subjects with a history of cholecystectomy or gallstones
5. Subjects who do not have suitable veins for multiple venepunctures/cannulations as assessed by the investigator or delegate at screening
6. Clinically significant abnormal clinical chemistry (including CK >1.5 × ULN), haematology or urinalysis as judged by the investigator (detailed in the clinical protocol)
7. Positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV Ab) or human immunodeficiency virus (HIV) 1 and 2 antibody results
8. Evidence of renal impairment at screening, as indicated by an estimated eGFR of <60 mL/min /1.73 m2 using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI; 2021) equation
9. Females of childbearing potential who are pregnant, lactating, or planning to become pregnant (all female subjects must have a negative highly sensitive urine or serum pregnancy test).
10. Subjects who have received any IMP in a clinical research study within the 90 days prior to Day 1, or less than 5 elimination half-lives prior to Day 1, whichever is longer
11. Subjects who have previously taken part in Part 1
12. Donation of blood or plasma within the previous 3 months or loss of greater than 400 mL of blood
13. Subjects who are taking, or have taken, any prescribed or over-the-counter drug or herbal remedies (other than up to 4 g of paracetamol per day and hormonal contraception and HRT) in the 14 days before first administration of study medication
14. Any contraindication to the use of digoxin and rosuvastatin
15. History of any drug or alcohol abuse in the past 2 years
16. Regular alcohol consumption in males >21 units per week and in females >14 units per week (1 unit = ½ pint beer, or a 25 mL shot of 40% spirit, 1.5 to 2 units = 125 mL glass of wine, depending on type)
17. A confirmed positive alcohol breath test at screening or admission
18. Current smokers and those who have smoked within the last 12 months
19. Current users of e-cigarettes and nicotine replacement products and those who have used these products within the last 12 months
20. A confirmed breath carbon monoxide reading of greater than 10 ppm at screening or admission
21. Confirmed positive drugs of abuse test result at screening or admission
22. Male subjects with pregnant or lactating partners or partners planning to become pregnant
23. Subjects who are, or are immediate family members of, a study site or sponsor employee
24. Failure to satisfy the investigator of fitness to participate for any other reason

Date of first enrolment
27/05/2025

Date of final enrolment
02/07/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Quotient Sciences
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Sponsor information

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IntraBio Inc.

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
IntraBio Inc.

Results and Publications

Publication and dissemination plan
1. Internal report
2. Publication on website
3. Submission to regulatory authorities

Intention to publish date
27/11/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because the results of this Phase I healthy volunteer study are commercially very sensitive. It is not appropriate to share the results of this study with other researchers at this time.

IPD sharing plan summary
Not expected to be made available