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A study in healthy men of the absorption of radiolabelled [14C]LTG-001, how the body breaks it down, and how quickly the body gets rid of it

Submission date
07/08/2025

Recruitment status
No longer recruiting

Registration date
29/09/2025

Overall study status
Completed

Last Edited
18/12/2025

Condition category
Other

[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 a new test medicine, LTG-001, to treat acute and chronic forms of pain. Acute pain is caused by injury, surgery, trauma or painful medical procedures, is short in duration, and disappears when the cause is resolved. Chronic pain is a constant and recurring pain that persists for 3 or more months. We feel pain when our body sends messages through nerves to the brain. The test medicine helps by blocking one of the pain pathways in the nerves, so the brain doesn't get as many pain signals.
Currently available medicines for pain, such as anti-inflammatory, anti-depressant, anti-epileptic and opioid drugs do not work for everyone and can have troublesome side effects. The development of new treatments that are effective in the management of acute and chronic pain is required to meet this unmet need.
In this study, we'll give healthy volunteers a single dose of the test medicine to find out how the body breaks down and gets rid of the test medicine. The test medicine will be radiolabelled - it will contain a small amount of radioactivity (Carbon-14) - so that we can track it in the body. We also want to get more information on whether the test medicine causes any important side effects.

Who can participate?
Healthy men aged 30-65 years

What does the study involve?
Volunteers will receive a single dose of radiolabelled test medicine, as capsules by mouth. They' ll stay in the clinic for up to 21 nights and take up to 7 weeks to finish the study. We'll collect blood and urine samples to do safety tests. Over a period of at least 14 days, we'll take many blood samples and volunteers will collect all their urine and faeces so that we can measure the amount of test medicine and its breakdown products.

What are the possible benefits and risks of participating?
Participants will get no medical benefit from taking part in this study. We hope that the development of a product to improve the treatment of acute and chronic pain will be of benefit to patients with this condition.
Volunteers may experience side effects from the test medicine. The test medicine is early in development so there is little information about its effects in humans. Full information on possible side effects is in the Participant Information Sheet and Informed Consent Form. 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.
Volunteers will be exposed to 0.0269 milliSieverts (mSv) of radioactivity during the study, which is equivalent to about 4 days' exposure to average background radiation in the UK (2.7 mSv per year). That amount of radiation poses negligible risk to the volunteers' health.
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'll be allowed no fluids.
The test medicine might harm unborn children, so all volunteers must follow the restrictions on donation of sperm and use acceptable contraception. Were a partner of a volunteer to become pregnant during the study, we would ask permission to follow up 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.
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 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?
Quotient Sciences Limited (UK)

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

Who is funding the study?
Latigo Biotherapeutics, Inc. (USA)

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

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
1012272

Protocol serial number
LTG-001-009, QSC303399

Study information

Scientific Title
An open-label, single-dose study designed to assess the mass balance recovery, metabolite profile and metabolite identification of [14C]LTG-001 in healthy male subjects

Study objectives
Primary objective:
To determine the mass balance of LTG-001 administered as a single oral dose of [14C]LTG-001.

Secondary objectives:
1. To perform metabolite profiling and structural identification from plasma, urine and faecal samples.
2. To determine the routes and rates of elimination of [14C]LTG-001.
3. To identify the chemical structure of each metabolite accounting for ≥10% of circulating total radioactivity (TR). An attempt will be made to identify greater than 80% of the radioactivity recovered in the urine and faeces.
4. To evaluate the extent of distribution of TR into blood cells.
5. To explore the pharmacokinetics (PK) of LTG-001 and total radioactivity following oral administration with [14C]LTG-001.
6. To provide additional safety and tolerability information for LTG-001.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/09/2025, Wales Research Ethics Committee (REC) 2 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0) 2922941119, +44 (0) 2922 940959; Wales.REC2@wales.nhs.uk), ref: 25/WA/0220

Study design
Open-label single-dose study

Primary study design
Interventional

Study type(s)
Safety, Other

Health condition(s) or problem(s) studied
This trial is in healthy volunteers

Interventions
This is a single-period, single-dose, non-randomised, open-label study. We'll give healthy male volunteers a single dose of test medicine to find out how the body breaks down and gets rid of the test medicine. The test medicine will be 'radiolabelled' - it will contain a small amount of radioactivity (Carbon-14) - so that we can track it in the body. We also want to get more information on whether the test medicine causes any important side effects. This study will take place at 1 non-NHS site in Nottingham. We plan to enrol 8 healthy men aged 30-65 years. Subjects will be admitted on Day -1 and receive a single oral dose of 300 mg of the test medicine radiolabelled with Carbon-14, as 3 x 100 mg capsules by mouth. They'll stay in the clinic for up to 21 nights. We'll collect blood and urine samples to do safety tests. Over a period of at least 14 days, we'll take many blood samples and volunteers will collect all their urine and faeces so that we can measure the amount of test medicine, its breakdown products and radioactivity. Subjects are expected to be involved in this study for approximately 7 weeks from screening to discharge.

Intervention Type
Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)
[14C]LTG-001 Capsule, 100 mg (NMT 1.5 MBq)

Primary outcome(s)
Total radioactivity (TR) measured using urine and faecal samples collected from Day 1 until mass balance criteria have been met

Key secondary outcome(s))
1. Metabolite profiling and identification (ID) measured using urine and faecal samples taken for from Day 1 until mass balance criteria have met
2. TR and PK and metabolite profiling and ID measured using plasma samples taken from Day 1 up to discharge from the clinical unit
3. TR measured using whole blood from Day 1 up to discharge from the clinical unit
4. Safety and tolerability measured using assessment of adverse events (AEs), physical examinations and change from baseline for vital signs, ECGs, and laboratory safety tests from screening up to discharge from the study

Completion date
28/11/2025

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. Aged 30 to 65 years inclusive at the time of signing informed consent
4. Must agree to adhere to the contraception requirements defined in the clinical protocol
5. Healthy male subjects 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. Urinalysis, ECGs and vital signs to be re-checked at admission/pre-dose
6. Body mass index (BMI) of 18.0 to 35.0 kg/m2 as measured at screening
7. Must have regular bowel movements (i.e. average stool production of ≥1 and ≤3 stools per day)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 years

Upper age limit

65 years

Sex
Male

Total final enrolment
8

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 particularly gastrointestinal (GI) disease, especially peptic ulceration, GI bleeding, ulcerative colitis, Crohn's Disease or Irritable Bowel Syndrome, neurological or psychiatric disorder, as judged by the investigator
4. History of GI surgery (with the exception of appendectomy or hernia repair unless it was performed within the previous 12 months)
5. Acute diarrhoea or constipation in the 7 days before the predicted Day 1. If screening occurs >7 days before Day 1, this criterion will be determined on Day 1. Diarrhoea will be defined as the passage of liquid faeces and/or a stool frequency of greater than three times per day. Constipation will be defined as a failure to open the bowels more frequently than every other day.
6. Subjects who do not have suitable veins for multiple venepunctures/cannulation as assessed by the investigator or delegate at screening
7. Clinically significant abnormal clinical chemistry, haematology or urinalysis as judged by the investigator. Subjects with Gilbert's Syndrome are not allowed
8. Positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV Ab) or human immunodeficiency virus (HIV) 1 and 2 antibody results
9. Evidence of renal impairment at screening, as indicated by an estimated creatinine clearance (CLcr) of <80 ml/min using the Cockcroft-Gault equation
10. Personal or family history of long QT syndrome or a QTcF interval on screening or pre-dose ECG >450 msec
11. 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
12. Radiation exposure, including that from the present study, excluding background radiation but including diagnostic x-rays and other medical exposures, exceeding 5 mSv in the last 12 months or 10 mSv in the last 5 years. No occupationally exposed worker, as defined in the Ionising Radiation Regulations 2017, shall participate in the study
13. Donation of blood or plasma within the previous 3 months or loss of greater than 400 ml of blood
14. 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) in the 14 days before IMP administration. Exceptions may apply, as determined by the investigator, if each of the following criteria are met: medication with a short half-life if the washout is such that no pharmacodynamic activity is expected by the time of dosing with IMP; and if the use of medication does not jeopardise the safety of the trial subject; and if the use of medication is not considered to interfere with the objectives of the study.
15. Subjects who have had a vaccine within 15 days before IMP administration
16. History of any drug or alcohol abuse in the past 2 years
17. Regular alcohol consumption in males >21 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)
18. A confirmed positive alcohol breath test at screening or administration
19. Current smokers and those who have smoked within the last 12 months
20. Current users of e-cigarettes and nicotine replacement products and those who have used these products within the last 12 months
21. A confirmed breath carbon monoxide reading of greater than 10 ppm at screening or admission
22. Confirmed positive drugs of abuse test result at screening or admission
23. Male subjects with pregnant or lactating partners
24. Subjects who are, or are immediate family members of, a study site or sponsor employee
25. Failure to satisfy the investigator of fitness to participate for any other reason

Date of first enrolment
09/10/2025

Date of final enrolment
26/11/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way
Ruddington Fields
Nottingham
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NG11 6JS

Sponsor information

Organisation
Latigo Biotherapeutics, Inc.

Funder(s)

Funder type
Industry

Funder Name
Latigo Biotherapeutics, Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository

IPD sharing plan summary
Stored in non-publicly available repository