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18F-LW223: A new tool for detecting inflammation in the body

Submission date
27/08/2025

Recruitment status
Recruiting

Registration date
31/10/2025

Overall study status
Ongoing

Last Edited
31/10/2025

Condition category
Other

[ ] 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
This project will study a new tool for scanning patients based on a highly specialised scanning technique called positron emission tomography (PET). PET allows for the study of different processes happening inside the human body by injecting a small amount of a substance into patients, i.e. a radiotracer. Our new radiotracer, [18F]LW223, was designed so it can highlight and localise inflammation inside the body. This could be useful, as inflammation plays a role in the development and progression of many common diseases.

Who can participate?
Healthy male individuals aged between 18 and 55 years.

What does the study involve?
In this study, we will be tracking [18F]LW223 signal inside the human body over time. This will involve a single PET scan for each healthy volunteer. During the scan we will collect blood and/or urine samples, to work out the best dose and to ensure [18F]LW223 signal is consistent across the population along with ensuring safety and tolerability of the compound within healthy volunteers.

What are the possible benefits and risks of participating?
Benefits:
Not provided at time of registration
Risks:
PET-CT Scan
Participants in this study will undergo one PET-CT scan. This scan is additional to what they would have if they did not take part in this study. These procedures use ionising radiation to form images of the body. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study may increase the chances of this happening by 0.05%. Following the PET injection, participants will be slightly radioactive for a few hours. They will be asked to avoid pregnant people and children for 6 hours after the PET scan. The radiation risks have been appraised by a Medical Physics Expert and justified by a Clinical Radiation Expert.

Allergic reactions to radiotracers are very rare (serious allergic reactions occur in 1 in 10,000 patients), but we have procedures in place for managing such reactions in line with Resuscitation Council UK Guidelines, and we will exclude participants who are known to have an allergy or sensitivity to any drug.

Peripheral Venous Cannulation
To give the radioactive tracer for the scan, a plastic tube (cannula) will be inserted into a vein in the participant's arm. This will be removed once the scan has finished. There is a small risk of bleeding, bruising and infection, but our staff are highly trained in their insertion and we follow a sterile procedure.

Arterial Line Insertion
To be able to take up to 26 arterial blood samples after injection of the radiotracer, a plastic tube (arterial catheter) will be inserted into an artery in the participant's wrist.
Risks of radial artery cannulation will be minimized by having the procedure performed by an experienced physician. The risk of infection will be reduced by careful cleansing of the skin prior to intravascular line insertion. Pain will be minimized through the use of local anaesthesia. Bleeding will be minimised after catheter removal by direct local pressure or application of a pressure dressing for a minimum of 10 minutes. Subjects will be provided a 24-hour emergency physician telephone number to call if they encounter pain, discoloration, numbness, tingling, coolness, discharge, or any other unusual symptom in the wrist or hand, or systemic symptoms such as fever or chills following the procedure. Subjects will be informed of potential problems to look out for and given procedures to follow should any problems occur.

Abnormal Findings
As part of the study, the scans will obtain images of the body. On rare occasions, we may see something which requires further investigation or treatment. If we find such an abnormality, we will contact the participant and their GP, and arrange further follow up if necessary. Although a major problem is unlikely, participants will be made aware that this may have consequences for treatment. Some incidental findings may also have implications for insurance and job or finances, and this will also be made clear.

We will ensure these risks are explained to each potential participant fully in the participant information sheet, and in person by the clinical research team.

Where is the study run from?
University of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
August 2025 to December 2027

Who is funding the study?
Medical Research Council (MRC) (UK)

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
1007539

Protocol serial number
AC23086

Study information

Scientific Title
18F-LW223: a superior TSPO PET radiotracer for a clinical breakthrough to detect regional tissue inflammation

Acronym
18F-LW223

Study objectives
Primary objective:
Assess the safety and tolerability of a single dose of 18F-LW223 in healthy volunteers.

Secondary objective:
1. To conduct quantitative assessments of radiation exposure to the whole body and its internal organs (dosimetry studies) in humans to identify best [18F]LW223 dose for subsequent clinical studies.
2. To confirm that [18F]LW223 binding to human TSPO is independent of the rs6971 polymorphism in vivo.
3. To confirm that [18F]LW223 of binding binds to single TSPO site in vivo.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 04/09/2025, North East- York Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 972 2503; york.rec@hra.nhs.uk), ref: 25/NE/0170

Study design
Interventional non randomized

Primary study design
Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied
Radiotracer to detect regional tissue inflammation

Interventions
PET-CT scan using [18F]LW223 radiotracer

Participants will undergo one PET-CT scan with duration between 2-6 hours depending on the cohort. During the scan, we will collect blood and/or urine samples. All participants will receive a follow up phone call one week after the scan.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
18F-LW223 [(R)-(N-sec-Butyl)-3-fluoromethyl-N-methyl-4-phenylquinoline-2-carboxamide]

Primary outcome(s)
Safety and tolerability based on the number and severity of adverse events at 27 months from approval

Key secondary outcome(s))
Utility of [18F]LW223 as a TSPO PET radiotracer at 27 months from approval defined based on:
1. [18F]LW223 effective dose measured in healthy adult males using whole-body biodistribution and pharmacokinetic studies
2. Low affinity binder (LAB) to high affinity binder (HAB) PET outcome measure ratio determined using quantitative kinetic modelling and uptake indices
3. Comparable binding kinetics in LAB, HAB and mix affinity binder (MAB) determined using quantitative kinetic modelling and uptake indices

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Male subjects between 18 and 55 years old, inclusive, at screening visit.
2. Provision of informed consent prior to any study-specific procedures.
3. Willing to undergo genotyping for the rs6971 genetic polymorphism to allow placement into the correct study cohort.
4. Must be surgically sterile (vasectomy) or practicing at least one of the following methods of contraception, and refrain from sperm donation, from radiopharmaceutical administration until 90 days after the radiopharmaceutical administration:
a. Partner(s) using an intrauterine device;
b. Partner(s) using hormonal contraceptives (oral, vaginal, parenteral or transdermal);

c. Subject and/or partner(s) using double-barrier method (condoms, contraceptive sponge, diaphragm, or vaginal ring with spermicidal jellies or creams);
d. Total abstinence from sexual intercourse as the preferred lifestyle of the subject; periodic abstinence is not acceptable.
5. Body Mass Index (BMI) between 18 to 35 kg/m², inclusive. BMI is calculated as weight in kilograms divided by the square of height measured in meters.
6. In good physical and mental health on the basis of medical history, physical examination, and routine laboratory measurements (i.e. without major or clinically relevant pathology), as judged by the Investigator.
7. For Cohort 2, subject is willing to allow the investigators to place an arterial catheter in the radial artery and has a readily palpable pulse.
8. Willing to refrain from consumption of caffeinated beverages from 48 hours prior to study radiopharmaceutical administration until the end of scanning session.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
Male

Key exclusion criteria
1. Inability or unwillingness to give informed consent.
2. History of claustrophobia or inability to tolerate supine position for PET/CT scans, determined by participant questionnaire at screening.
3. Exposure to >10 mSv of ionizing radiation within the last 12 months, determined by reviewing data in the TOPS registry and electronic health records at screening.
4. Participation in more than 4 other drug trials in the 12 months prior to the study, determined by participant questionnaire and records review.
5. Receipt of an investigational product within a time period equal to 10 half-lives (if known), or within 6 weeks prior to the scanning visit.
6. Use of any over-the-counter medication, prescription medications, vitamins and/or herbal supplements within a time period equal to 6 half-lives (if known), or within 2 weeks prior to the scanning visit.
7. Self-assessed use of tobacco or other nicotine-containing products within 6 months preceding the screening visit, and a positive cotinine test at the scanning visit.
8. Self-assessed history of drug or alcohol abuse within 2 years prior to the screening visit. Alcohol abuse is defined as use of more than 28 units of alcohol per week or a positive drug /alcohol test at the scanning visit.
9. Known history of significant sensitivity or allergy to any drug, determined by questionnaire

and records review.
10. Impaired renal function with eGFR <60 mL/min/1.73m² as measured at screening.
11. Clinically significant abnormal ECG or QTcF >480 ms at screening, as determined by the investigator.
12. Positive test result for HAV-IgM, HBsAg, HCV Ab, or HIV Ab at screening.
13. Donation or loss of ≥400 mL blood volume (including plasmapheresis), or transfusion of any blood product <8 weeks prior to study start.
14. History of seizures (except single febrile seizure in childhood) or first-degree relative with confirmed epilepsy.
15. History of psychiatric diseases or disorders, determined by questionnaire and records review:
a. Major depressive episode within past 2 years (DSM-IV-TR);
b. Serious and persistent mental illness: bipolar disorder, schizophrenia, schizoaffective disorder, PTSD, OCD, or borderline personality disorder;
c. Significant current suicidal ideation (C-SSRS questions 4 or 5), or any history of suicide attempts.
16. Known family history of long-QT syndrome or unexplained sudden death.
17. History of gastric surgery, cholecystectomy, vagotomy, bowel resection, or any procedure affecting GI motility, pH, or absorption.
18. Serious illness requiring hospitalisation or surgery within 30 days prior to study drug administration.
19. Individuals designated as classified persons under the Ionising Radiations Regulations 2017 by their employer.
20. Volunteers who completed participation in the [18F]LW223 TSPO PET radiotracer trial are not eligible for re-enrolment.
21. Volunteers who experience an adverse event during the screening visit will be excluded from the trial and will not proceed to the scanning visit.
22. If an adverse event occurs during the scanning visit before IMP administration, a clinician will assess eligibility to continue.

Date of first enrolment
01/09/2025

Date of final enrolment
01/09/2028

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Old Dalkeith Road
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Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
We are committed to share all data not covered by confidentiality clauses in a timely manner, submitting that data to relevant recognised public repositories wherever possible. To enable data sharing and ensure long-term discoverability and accessibility, the imaging data, together with relevant and appropriate metadata, will be offered to Edinburgh DataShare. Edinburgh DataShare will, on acceptance of the data, supply a DOI and suggested citation to be used by anyone citing this data in the future. It will also undertake to ensure that the data remains discoverable, accessible, and reusable for as long as practically possible. Deposited data will be made available in accordance with the RCUK Open Access policy, except if data is considered sensitive to the research and not suitable for open access or specific embargo periods have been agreed. We will follow the MRC policy on research datasharing.

The principal investigator will be responsible for the governance of the research data access during the project period.

IPD sharing plan summary

Available on request, Stored in non-publicly available repository