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The LITE study: shining LIGHT on Parkinson's disease

Submission date
13/06/2025

Recruitment status
Recruiting

Registration date
17/06/2025

Overall study status
Ongoing

Last Edited
16/07/2025

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
Scientists are still working to understand fully why Parkinson's disease (PD) happens. It is likely to be due to, or at least in part due to, a combination of genetic and environmental factors as well as ageing. There is no test for diagnosing PD, for measuring how it progresses, or predicting what the outcome for people living with PD will be. As new approaches to treatments are being tested in clinical trials, we don't know whether these new treatments might help all people with PD or only a smaller group of people with PD.
The LITE study is important as it will help to fill these critical gaps in our knowledge. The LITE study is especially important as it will be collecting a lot of biological samples, imaging data and information from a large group of people, with and without PD. Scientists will be able to look at all the information we collect, and their work will add to our general knowledge about PD

Who can participate?
Patients aged 18 years and over with PD, and healthy volunteers

What does the study involve?
You will be invited to come to the Ninewells Hospital, Dundee (or one of the global sites) to have biological samples taken, a Magnetic Resonance Imaging scan (MRI) brain scan, a dopamine transporter (DaT) SPECT brain scan and assessments of PD signs and symptoms (even if you don' t have PD). Details of all the assessments are given below.
Before you have any assessments, we will ask you to complete a consent form to say that you want to take part in the study. You will be able to speak to a study doctor before you sign the consent form if you want.
You will have all these assessments whether or not you have PD: review of your medical history, medications and treatments, family history, ethnicity, physical and neurological examination, smell identification test, questionnaires, blood samples, urine sample, sebum sample, breath sample, skin biopsies, cerebrospinal fluid sample, MRI scan and DaT scan.

What are the possible benefits and risks of participating?
The main benefit of taking part will be that you will be contributing to the understanding of PD and eventually the possible development of new treatments which could benefit you and future patients. The study may not immediately benefit you, but if the results of the study are positive

this may improve how we treat people with PD.
There are a lot of assessments for you to complete for the study and this may be tiring for you. We can arrange for the assessments to be split over 2 or more days, so you don't get too tired. You can ask your study team to stop the assessments at any time and come back another day to finish them. We can also arrange the visits so that you have a "rest day" between visits. All of the medical procedures outlined in the PIS have an element of risk and this is detailed further in the information sheet. Your study doctor will discuss these in detail with you ahead of participating and during the informed consent process.

Where is the study run from?
The study is led by the University of Dundee at Ninewells Hospital. This will be the only UK site. There will be several other sites globally.

When is the study starting and how long is it expected to run for?
October 2024 to August 2027

Who is funding the study?
Michael J. Fox Foundation for Parkinson's Research (USA)

Who is the main contact?
Dr Esther Sammler, e.m.sammler@dundee.ac.uk

Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
351205

Protocol serial number
CPMS 66112

Study information

Scientific Title
The MJFF LRRK2 Investigative Therapeutics Exchange (LITE) Study: the LITE study

Acronym
MJFF:LITE

Study objectives
The proposed LITE study is the translational pillar of the LITE Initiative and is designed as an observational, multi-center international study with the additional option for follow-up. The LITE study aims to discover and test new biological markers for LRRK2-driven Parkinson's disease (PD) in various genetic (monogenic) PD and non-genetic (idiopathic) PD populations, people at

risk for PD and healthy controls and correlate these with clinical and imaging features of disease state and progression.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/05/2025, East of Scotland Research Ethics Service (Tayside Medical Science Centre, Residency Block, Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, United Kingdom; +44 (0)1382 383900; tay.eosres@nhs.scot), ref: 25/ES/0023

Study design
Cross-sectional observational multi-center international study

Primary study design
Observational

Study type(s)
Other

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

Interventions
Participants will undergo clinical (motor, neuropsychiatric and cognitive) and imaging assessments and will donate biological samples including blood (e.g. plasma, Peripheral blood mononuclear cells (PBMCs), neutrophils and monocytes), urine, skin biopsies and skin swabs, breath and CSF for comprehensive biological sample analysis. Every participant will also undergo genetic testing for PD-relevant genes.

Intervention Type
Other

Primary outcome(s)
1. Lysosomal lipids, metabolites and proteins in enriched lysosomal fractions from peripheral blood immune cells, measured using targeted and untargeted mass spectrometry in tagless LysoIP samples isolated from peripheral blood mononuclear cells (PBMCs) and monocytes at a single cross-sectional timepoint
2. LRRK2 levels and LRRK2 kinase activity in peripheral blood immune cells, measured using a targeted mass spectrometry assay in peripheral blood monocytes and neutrophils
3. Presence of misfolded, aggregation-prone alpha-synuclein species, measured using an alpha-synuclein seed amplification assay in cerebrospinal fluid and in skin homogenates collected at the study visit

Key secondary outcome(s))
1. BMP (bis(monoacylglycerol)phosphate) levels in urine, measured using targeted mass spectrometry from urine samples collected at a single cross-sectional timepoint
2. Mass-spectrometry profiles in cerebrospinal fluid (CSF), measured using data-independent acquisition (DIA) mass spectrometry from CSF collected at the study visit
3. Mass-spectrometry profiles in plasma, measured using high-resolution mass spectrometry-based lipidomics from plasma collected at a single cross-sectional timepoint

4. Mass-spectrometry profiles in urine, measured using untargeted ultra-high performance liquid chromatography – mass spectrometry (UHPLC-MS) from urine samples collected at the study visit
5. Genetic variants associated with Parkinson's disease, measured using next-generation sequencing (NGS) from genomic DNA isolated from whole blood at the study visit

Completion date
31/08/2027

Eligibility

Key inclusion criteria
Parkinson's disease group:
1. Age >/=18 years
2. Willingness to undergo genetic testing
3. Able to provide informed consent
4. Diagnosis of PD meeting the Movement Disorder Society Clinical Diagnostic Criteria for clinically established PD
5. Braykiesia and resting tremor or rigidity

Additional inclusion criteria for PD subgroups:
1. Genetic PD: confirmation of carrier status of a pathogenic or probable pathogenic variant in LRRK2, VPS35, Rab32, GBA1 or other monogenic form of PD.
2. Non-genetic PD (Idiopathic PD): absence of carrier status of a pathogenic or probable pathogenic variant in LRRK2, VPS35, Rab32, GBA1 or other monogenic form of PD.

Non-Parkinson's disease group:
1. Age >/=18 years
2. Willingness to undergo genetic testing
3. Able to provide informed consent

Additional inclusion criteria for non-PD subgroups:
1. No PD and no genetic carrier status for PD ('healthy controls')
2. Absence of carrier status of a pathogenic or probable pathogenic variant in LRRK2, VPS35, Rab32, GBA1 or in any other clearly PD-related gene
3. Absence of a first-degree relative with PD (e.g., biological parent, sibling, child) or multi-incident family history of PD

No PD but non-manifesting pathogenic variant carrier status:
1. Confirmation of carrier status of a pathogenic or probable pathogenic variant in LRRK2, VPS35, Rab32, GBA1 or other monogenic form of PD

No PD but positive family history of PD:
1. First-degree relative with PD (e.g., biological parent, sibling, child) or multi-incident family history of PD
2. Unknown genetic carrier status of a pathogenic or probable pathogenic variant in LRRK2, VPS35, Rab32, GBA1 or other monogenic form of PD

Participant type(s)
Healthy volunteer, Patient, Other

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Exclusion criteria for all participants with PD:
1. A clinical diagnosis of dementia as determined by the investigator
2. Clinical evidence of atypical Parkinsonism (e.g., multiple-system atrophy or progressive supranuclear palsy) or evidence of drug-induced Parkinsonism
3. Previously obtained Magnetic Resonance Imaging (MRI) scan with evidence of clinically significant neurological disorder (in the opinion of the Investigator)
4. Any other reason (medical or psychiatric condition or lab abnormality) that, in the opinion of the investigator, would render the participant unsuitable for study enrollment
5. Participation in a clinical trial testing an investigational medicinal product for PD that could interfere with the study investigations, e.g. LRRK2 or lysosome targeting IMPs (in the opinion of the investigator)

Exclusion criteria for MRI and DAT imaging with PD:
1. Pregnant, lactating or planning pregnancy during the study. Pregnancy test to be carried out on day of scan for women of childbearing potential. Iodine allergy is exclusionary

Exclusion criteria for all participants without PD:
1. Symptomatic PD syndromes due to either drugs (e.g., metoclopramide, flunarizine, neuroleptics) or metabolic disorders (e.g., Wilson’s disease), encephalitis
2. Clinical evidence of atypical Parkinsonism (e.g., multiple-system atrophy or progressive supranuclear palsy)
3. A clinical diagnosis of dementia as determined by the investigator
4. Previously obtained Magnetic Resonance Imaging (MRI) scan with evidence of clinically significant neurological disorder (in the opinion of the Investigator)
5. Any other reason (medical or psychiatric condition or lab abnormality) that, in the opinion of the investigator, would render the participant unsuitable for study enrollment

Exclusion criteria for MRI and DAT imaging without PD:
Pregnant, lactating or planning pregnancy during the study. Pregnancy test to be carried out on day of scan for women of childbearing potential. Iodine allergy is exclusionary

Date of first enrolment
30/06/2025

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Neuroprogressive and Dementia Network - NHS Tayside
Clinical Research Centre
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Sponsor information

Organisation
University of Dundee

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
Michael J. Fox Foundation for Parkinson's Research

Alternative Name(s)
Michael J. Fox Foundation, Fundación Michael J. Fox, The Michael J. Fox Foundation for Parkinson's Research, The Michael J. Fox Foundation, Michael J Fox Foundation for Parkinson's Disease Research, Michael J Fox Foundation for Parkinson's Research, The Michael J Fox Foundation for Parkinson's Research, MJFF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

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 (to be confirmed). The data sharing plan will be made available at a later date.

IPD sharing plan summary
Stored in non-publicly available repository