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Collecting high-quality biomaterial from patients with neurodegenerative diseases and controls for diagnostic and prognostic biomarker investigation/validation, therapeutic applications and other research activities

Submission date
16/09/2025

Recruitment status
Recruiting

Registration date
03/11/2025

Overall study status
Ongoing

Last Edited
04/12/2025

Condition category
Nervous System Diseases

[ ] 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

As the global population gets older, age-related brain diseases, like Alzheimer's disease, Parkinson's disease and amyotrophic lateral sclerosis (ALS), are becoming more common. These conditions are often hard to diagnose early, and mistakes are frequent. When people are seen at specialist dementia clinics, about 1 in 4 with Alzheimer's disease are incorrectly diagnosed. In some cases, these diseases are caused by inherited genetic mutations, but this is relatively rare (~ 20% of Parkinson's cases have a clear genetic cause). Most cases happen for reasons that are not fully understood yet. This makes accurate diagnosis even more important and more challenging. Many degenerative brain diseases urgently need better ways to diagnose them earlier and track how well treatments are working (ideally through simple, non-invasive tests like blood samples). This study aims to better understand what causes neurodegenerative diseases like Alzheimer's disease and Parkinson's disease, trying to understand what makes each disease unique, while also separating these findings from changes simply related to aging. The study's researchers have discovered tiny particles in the blood (and potentially in other body fluids such as urine) that show promise as a new type of biomarker, a biological indicator that can help detect diseases more accurately in people who already have symptoms. Excitingly, they may also help spot people at risk before symptoms appear and track how the disease is progressing. This study is focused on gathering more samples from individuals with Alzheimer's disease and Parkinson's disease. This will help evaluate the feasibility of expanding the study to larger populations and potentially extending it to other diseases in the future. The study is also looking to identify new targets for future therapies. The focus is on finding biomarkers that can help predict who may develop a disease, diagnose it more accurately, and track how it progresses or responds to treatment. There is strong evidence that treatments for these diseases work best if started early. That is why there is an urgent need for simple, reliable tests using easily collected samples like blood and urine that can detect the disease in its earliest stages and monitor how it changes.

Who can participate?
Adult patients with a neurodegenerative condition and healthy volunteers who are aged 18 or older, of any gender, ethnicity, or background.

What does the study involve?
All participants will be identified by trained healthcare staff who understand how to assess mental capacity and follow up-to-date good clinical practice (GCP) guidelines. Some participants will not yet show symptoms of disease. These individuals are often identified when there is a known family history of the disease, especially if a genetic mutation linked to the disease has already been found in a close relative (such as a parent or sibling). Healthy volunteers will also be included in the study. These may be first-degree relatives (parents, siblings, or children) of patients, as well as partners, carers, or unrelated individuals. They may be recruited at the same clinics, either through established procedures or by expressing interest themselves (often because they are attending appointments with family members or loved ones).

Well-characterised disease cohorts are planned in Alzheimer's disease and Parkinson's disease, aiming to separate disease-specific features from general changes of age-related organ degeneration. Differences in expression levels of biomarkers derived from blood and urine derivatives between different groups (diseases and healthy controls) will be assessed.

The following types of samples will be collected from participants:
Blood Samples
• These may be taken during a routine medical appointment or during an extra visit, if needed.
• Blood will be used for research to find disease-specific biomarkers.
Urine Samples
• Urine will usually be collected at the same time as the blood sample.
• Like blood, urine will be used for biomarker research and other scientific studies.

Follow-Up Samples (Optional for patients)
• Some participants may be asked to give another sample within 6 months of the first one.

Participants will not undergo any treatment as part of this study. Any treatments they receive will be part of their standard medical care.

What are the possible benefits and risks of participating?
There may not be an immediate clinical benefit to participants in this study. However, the information gathered in this study will enhance our understanding and improve the treatment of people with rare disorders in the future, contributing to ongoing research in the UK and globally.

All results generated from this study, including scientific publications and intellectual property, will be carefully managed and shared as appropriate.

There are almost no risks to participants in this study. Trained healthcare staff will explain the procedures involved in collecting the sample. Some discomfort may be experienced during the withdrawal of blood samples.

Where is the study run from?
The study will be conducted and managed by the Surrey and Borders Partnership NHS FT (SABP) for the recruitment of Alzheimer's disease and Parkinson's disease patients and will be terminated after 3 years at the latest, when sufficient cohorts have been recruited to determine the validity of the biomarkers.

When is the study starting and how long is it expected to run for?
June 2025 to August 2028

Who is funding the study?
Vesalic Limited, UK

Who is the main contact?
1. Chloe Walsh, Research Co-Ordinator at SABP, research@sabp.nhs.uk
2. Pierpaolo Ala, Senior Project Manager at Vesalic, pier@vesalic.com

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Central Portfolio Management System (CPMS)
68450

Integrated Research Application System (IRAS)
355533

Study information

Scientific Title
Investigation of novel biomarkers and therapeutics in neurodegenerative diseases

Study objectives
This study aims to investigate the potential causes and mechanisms of neurodegenerative diseases, focusing on the development of predictive, diagnostic and prognostic biomarkers, and potential therapeutic targets.

Since strong preclinical evidence suggests that effective therapy should be delivered as early as possible to slow disease progression, there is an urgent need for sensitive and responsive biomarkers that accurately quantify changes and can be assessed non-invasively from different body fluids, such as blood and urine, with stability and reliability. Both blood and urine will be collected from patients and healthy control individuals (HC).

This study will enable biomarker studies in patients in the UK living with a number of neurodegenerative conditions to add to the research currently being conducted in the UK and worldwide and help with the discovery and systematic assessment of early biomarkers that predict disease progression, and with identifying novel therapeutic options for these patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/06/2025, Health and Care Research Wales (Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2922 941107, (0)2922 940968; Wales.REC7@wales.nhs.uk), ref: 25/WA/0178

Study design
Single-centre observational study

Primary study design
Observational

Study type(s)
Diagnostic, Prevention

Health condition(s) or problem(s) studied
Assessment of early biomarkers that predict disease progression and help identifying novel therapeutic options for patients with Alzheimer's Disease (AD) and Parkinson's Disease (PD).

Interventions
Participants will meet face-to-face with a researcher for this study. They will have received the PIS in advance and will have an opportunity to go through any questions before they sign the consent form. Once the consent form has been signed, participants will be asked some questions about their demographics and their health. The questions are brief and should take less than 15 minutes to complete. Following this, they will be asked to provide a blood sample and a urine sample. The urine sample may be collected at the same visit as the blood sample. The visit will take less than 30 minutes. Participants will have the option to be contacted within 6 months from the first sample collection and donate an additional follow-up sample. Family members of participants and healthy control volunteers will only have samples taken once.

Intervention Type
Other

Primary outcome(s)
Extracellular vesicles (EVs) will be isolated from the serum samples, and their molecular contents will be analyzed using quantitative liquid chromatography–mass spectrometry (LC-MS). The mass spectrometry data—reflecting the expression levels of biological particles contained within the EVs—will undergo statistical evaluation and be processed by a custom-built artificial intelligence (AI) model designed to differentiate between patients and healthy controls. The study cohort will consist of treatment-naïve individuals at baseline and patients who have initiated treatment at either the 6- or 12-month time points. The study is planned to last 3 years, comprising a 9-month enrolment period followed by a 6-month follow-up for each participant.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/08/2028

Eligibility

Key inclusion criteria
1. Signed informed consent form
2. Adults of any gender, ethnicity or socio-economic group, with any of the mentioned conditions, aged 18 years and above
3. Participants who can provide informed consent for taking blood and/or urine as required
4. Participants who can have a blood and/or urine sample taken
5. Participants who have an established diagnosis of the mentioned neurodegenerative conditions
6. First-degree relatives (parents, siblings, children) of patients with any of the mentioned conditions
7. Partners/carers and other healthy control volunteers

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Participants who are currently involved in interventional clinical trials
2. Participants with severe intellectual impairment, who would be unable to cooperate and consent

Date of first enrolment
01/08/2025

Date of final enrolment
01/08/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Surrey and Borders Partnership NHS Foundation Trust
18 Mole Business Park
Randalls Road
Leatherhead
England
KT22 7AD

Sponsor information

Organisation
Vesalic Limited

Funder(s)

Funder type
Industry

Funder Name
Vesalic Limited

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication