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Stomach function in Parkinson's disease: a feasibility study

Submission date
09/01/2025

Recruitment status
No longer recruiting

Registration date
13/01/2025

Overall study status
Completed

Last Edited
30/12/2025

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
Parkinson's disease (PD) is the second most common neurodegenerative disease and affects 1% of people over the age of 60 years in industrialised countries. In Aotearoa New Zealand, the number has increased from about 7,000 in 2006 to about 11,000 in 2020.
There is significant diversity in symptoms in people with PD which encompass the conventional movement symptoms including tremor and rigidity. Over the past decade, there has been increasing recognition that non-movement symptoms have a more profound and negative impact on quality of life and wellbeing than movement problems in PD. Many of these affect the digestive system including the stomach, and these symptoms can impair dietary intake and negatively impact nutritional health.
This study aims to explore how feasible it is to conduct a study investigating the use of a device (body surface gastric mapping) to explore gastric (stomach) symptoms in people with PD.

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

What does the study involve?
Each participant is invited to one visit only. Participants will be asked to fast overnight for 6-8 hours and to arrive at the University of Auckland in the morning time at a pre-arranged time. They are asked to take all of their usual medications at home before their visit and to bring any medications to take during the visit. They are welcome to bring a member of their family, a caregiver, whānau or friend to the visit and they can stay with the participant during the visit. Height, weight and blood pressure will be measured and participants will be asked some questions and also to complete a number of questionnaires about their PD. Some measurements will be taken to record their movement.
They will be asked to recline on a comfortable chair and a device will be placed on the stomach that measures electrical responses. This is called a body surface gastric mapping device. The sensors are non-invasive, and participants are unlikely to feel much when measurements are being taken. The sensors are positioned and worn like an item of clothing. Participants are given a meal of a muesli bar and a milky drink and measurements will be taken for the next 4 hours. When the study is over, participants and caregivers will be offered lunch before going home.

What are the possible risks and benefits of participating?
The results will help to inform the development of further studies and trials. There are no significant benefits and no significant risks.

Where is the study run from?
The study is being run from the Liggins Institute at the University of Auckland (New Zealand)

When is the study starting and how long is it expected to run for?
May 2023 to May 2025

Who is funding the study?
1. Health Research Council of New Zealand
2. University of Auckland (New Zealand)

Who is the main contact?
Dr Fiona Lithander, fiona.lithander@auckland.ac.nz

Contact information

Type(s)
Principal investigator

Contact name
Dr Fiona Lithander

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
2024 EXP 20400

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2024 EXP 20400

Study information

Scientific Title
Gastric function in Parkinson’s disease: a feasibility study

Acronym
GastricPD

Study objectives
To test the feasibility of the use of a medical technology (body surface gastric mapping and symptom tracking) to measure gastric symptoms and electrophysiology in Parkinson's disease.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/05/2023, Southern Health and Disability Ethics Committee (133 Molesworth Street, Wellington, 6011, New Zealand; +64 (0)4 496 2000; hdec@health.govt.nz), ref: 2024 EXP 20400

Study design
Observational feasibility study

Primary study design
Observational

Study type(s)
Other

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

Interventions
Each participant is invited to one visit only. Participants will be asked to fast overnight for 6-8 hours and to arrive at the University of Auckland in the morning time at a pre-arranged time. They are asked to take all of their usual medications at home before their visit and to bring any medications to take during the visit. They are welcome to bring a member of their family, a caregiver, whānau or friend to the visit and they can stay with the participant during the visit.

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Intervention Type

Other

Primary outcome(s)
1. Recruitment rate, number of eligible participants, and length of time taken to recruit 10 participants measured using standard questions by 6 months.
2. Feasibility and acceptability of the measurement of gastric symptoms using the body surface gastric mapping device in 10 participants using existing questions by 6 months

Key secondary outcome(s))
1. Participant acceptability of completion of questionnaires listed here, assessed using standard questions at baseline
2. Quality of life measured using Parkinson's Disease Questionnaire 8 at baseline
3. Motor and non-motor symptoms measured using the Movement Disorder Society Unified Parkinson's Disease Rating Scale (MDS UPDRS) at baseline
4. Non-motor symptoms measured using the Movement Disorder Society Non-Motor Symptom Rating Scale (MDS NMS) at baseline
5. Gastrointestinal symptoms measured using the Gastrointestinal Symptom Rating Scale at baseline
6. Gastrointestinal symptoms measured using the MDS Gastrointestinal Dysfunction Scale for Parkinson's Disease at baseline
7. Dietary intake measured using intake24 at baseline
8. Gastric electrophysiological and symptom response to a standard test meal in Parkinson's up to 4 hours post consumption of the test meal compared with a matched control group

Completion date
12/05/2025

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. A diagnosis of idiopathic PD, diagnosed by a neurologist
3. Available to attend the Liggins Institute at the Grafton campus of the University of Auckland
4. The mental capacity to consent to participate in this research

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
10

Key exclusion criteria
1. People with medical, cognitive, or psychosocial issues that would preclude compliance with the protocol, confirmed by a principal investigator or neurologist
2. Co-enrolment in another study or trial that, in the opinion of the principal investigators, would interfere with adherence to study requirements

Date of first enrolment
04/02/2025

Date of final enrolment
12/05/2025

Locations

Countries of recruitment
New Zealand

Study participating centre
Liggins Institute, University of Auckland
85 Park Road
Grafton
Auckland
New Zealand
1123

Sponsor information

Organisation
University of Auckland

ROR
https://ror.org/03b94tp07

Funder(s)

Funder type
Research council

Funder Name
Health Research Council of New Zealand

Alternative Name(s)
HRCnz, Health Research Council of New Zealand (HRC), HRCNewZealand, HRC New Zealand, HRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
New Zealand

Funder Name
University of Auckland

Alternative Name(s)
University of Auckland, New Zealand, UoA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
New Zealand

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the principal investigator Dr Fiona Lithander (fiona.lithander@auckland.ac.nz)

IPD sharing plan summary
Available on request