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Biomarkers and rapid imaging in dementia diagnosis

Submission date
30/10/2023

Recruitment status
Recruiting

Registration date
21/02/2024

Overall study status
Ongoing

Last Edited
21/01/2026

Condition category
Mental and Behavioural Disorders

[ ] 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
MRI is an essential part of the diagnostic workup in dementia, however, the time taken and cost limit its availability. Reduction in scan time will solve these issues. This study aims to develop an ultra-fast MRI scan cutting the gold-standard MRI scan from 30 to 7 minutes, with these scans providing non-inferior images to aid in dementia diagnosis.

Who can participate?
Patients referred to the National Hospital for Neurology and Neurosurgery

What does the study involve?
The study involves a standard clinical MRI scan (30 minutes) with an additional 7 minutes for the ultra-fast scan, donation of a blood sample and 10 minutes of neuropsychology

What are the possible benefits and risks of participating?
There is no direct benefit for participating in the study. Some people experience minor discomfort, bruising or swelling following a blood draw. There is also a small risk of developing an infection at the site of blood draw. MRI scans may feel slightly uncomfortable due to the noise the machine makes. The table you lie on may feel hard, and the room may be cool, but the medical team will do everything they can to make you comfortable and blankets may be provided. You may be tired or sore from lying
in one position for a long time. Some people experience claustrophobia when having a scan, but the medical team will do whatever they can to help you relax before and during the scan. The MRI scanner produces loud tapping, knocking, chirping and squeaking sounds during the scans. Before your scan, the technicians will give you disposable foam ear plugs and headphones to wear to protect your hearing from the loud noise. Cognitive testing can be mentally tiring but is unlikely to cause any harm.

Where is the study run from?
National Hospital for Neurology and Neurosurgery (UK)

When is the study starting and how long is it expected to run for?
August 2021 to June 2026

Who is funding the study?
1. Biogen
2. Alzheimer's Society
3. Rosetrees Trust

Who is the main study contact?
1. Millie Beament, m.beament@ucl.ac.uk
2. Prof. Nick Fox, n.fox@ucl.ac.uk

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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)
291170

Protocol serial number
CPMS 51048, IRAS 291170

Study information

Scientific Title
Biomarkers & accelerate magnetic resonance imaging for dementia diagnosis

Acronym
B-RAPIDD

Study objectives
There is overwhelming pressure on healthcare systems to provide wider and more timely access to a dementia diagnosis. Structural MRI scans are an essential part of the diagnostic workup in dementia but their availability is confounded by their price and time taken. Making a substantial reduction in scan time would tackle these issues and mean that MRI would be available to most cases. This study develops an ultra-fast scanning protocol shortening scan time from 30 minutes to 7 minutes without impacting image quality. We will assess the ability of ultra-fast MRI to aid in dementia diagnosis and measure change over time, over short and longer intervals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/01/2022, London - Hampstead Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8248, +44 (0)207 104 8284, +44 (0)207 104 8227; hampstead.rec@hra.nhs.uk), ref: 21/LO/0815

Study design
Single-centre cross-sectional observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Dementia

Interventions
170 participants from the cognitive disorders clinic at the National Hospital for Neurology and Neurosurgery (UCLH) will be recruited. These participants are due to have a same-day MRI scan which takes 30 minutes, this study adds an additional 7 minutes in scanning time. They will also be asked to provide a blood sample and undergo a brief neuropsychological examination.

Participants in the longitudinal sub-studies will have the same as above at their first visit, with repeat scanning at subsequent visits, as well as optional blood sample collections.

Intervention Type
Other

Primary outcome(s)

Non-inferiority of ultra-fast MRI compared to gold standard MRI assessed using a 5-point Likert scale at baseline

Key secondary outcome(s))
1. Stability of ultra-fast MRI compared to gold standard MRI, assessed using a 5-point Likert scale at 2 weeks to 2 months
2. Ability of ultra-fast MRI to track longitudinal change compared to gold standard MRI, assessed using a 5-point Likert scale at 1 year
3. Blood biomarkers assessed by immunoassays at baseline, 2 weeks to 2-month interval and 1-year interval

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. An individual with ability to engage in the decision to participate in the research study and provide informed consent
2. Aged 18 years old and above

Main study: Patients attending the CDC at NHNN and at Darent Valley Hospital who are due to have a standard-of-care MRI of the brain as part of their routine investigation.
Sub-study 1: Participants in other REC approved studies, who are scheduled for a planned MRI brain scan
Sub-study 2: Healthy controls recruited through spouses/partners of patients, individuals who are included on the DRC Research Register and Join Dementia Research and patients attending the CDC at NHNN and at Darent Valley Hospital
Sub-study 3: Participants recruited to the main study who are happy to be contacted about follow-up study procedures

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment

0

Key exclusion criteria
1. Unable to tolerate a routine MRI scan plus a 7-minute fast-MRI scan
2. Unable to tolerate draw blood by venepuncture

Date of first enrolment
21/03/2022

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
National Hospital for Neurology & Neurosurgery
Queen Square
London
England
WC1N 3BG

Sponsor information

Organisation
University of London

ROR
https://ror.org/04cw6st05

Funder(s)

Funder type
Industry

Funder Name
Biogen

Alternative Name(s)
Biogen Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Alzheimer's Society

Alternative Name(s)
alzheimerssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
Rosetrees Trust

Alternative Name(s)
Rosetrees, Teresa Rosenbaum Golden Charitable Trust

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date