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Thinking and memory changes in older people after emergency hospital treatment

Submission date
04/08/2023

Recruitment status
No longer recruiting

Registration date
21/09/2023

Overall study status
Ongoing

Last Edited
16/06/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The study aims to understand what causes new or worsened confusion (so-called delirium) in older people, on admission to hospital with an acute illness. We want to understand why some people get delirium in hospital but then recover well or which patients do not recover well from their illness and are at high risk of future problems with memory and thinking (cognitive impairment or dementia) over the next 3 years.

Who can participate?
Older people aged 70 years or above admitted to hospital or same day emergency care (Oxford University Hospitals or Royal Berkshire Foundation Trusts) with an acute illness

What does the study involve?
Collection of clinical information, cognition, frailty and mobility questionnaires and assessments, one blood sample (approx. 20 mls equivalent to 4 teaspoons) and CT brain imaging (OUHFT only) from participants and from their electronic health records while in hospital (baseline). Follow-up will be clinic visits (or home, virtually or by telephone as appropriate) at 3 months, I year and 3 years for one hour of further questionnaires and assessments of health status, cognition, frailty and mobility. There would be one further blood sample (20mls) taken at 3 months. An informant (family member or carer) will be identified while the participant is in hospital (someone who knows the participant for at least 10 years) to complete two short questionnaires (IQCODE and Neuropsychiatric Inventory) while the participant is in hospital and again at the 3 year visit.

What are the possible benefits and risks of participating?
The benefits for participants include: all study assessments will be added to their electronic health records which may help their direct clinical team with their care. The follow-up provides a health check that normal clinical care may not provide. Participants may gain benefit from participating in greater interaction with researchers and may find the research interesting. With participants permission results of the follow-up assessments may also be provided to their GP that may help with their clinical care. The study is deemed low risk and does not involve any kind of intervention that would carry significant risks to participants' health. There may be a small risk

of becoming anxious during assessments but the research team are experienced in recognising and lessening anxiety. There is the possibility of discomfort/bruising at the site where blood is taken.

Where is the study run from?
Wolfson Centre for Prevention of Stroke and Dementia, Nuffield Department of Clinical Neurosciences, University of Oxford (UK).

When is the study starting and how long is it expected to run for?
December 2021 to December 2027

Who is funding the study?
NIHR i4i programme grant (NIHR204290) and John Fell Fund, University of Oxford (No 0012734) (UK)

Who is the main contact?
Professor Sarah Pendlebury, sarah.pendlebury@ndcn.ox.ac.uk

Contact information

Type(s)
Principal investigator

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Prof Sarah Pendlebury

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
314002

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 56808, IRAS 314002

Study information

Scientific Title
Oxford and Reading cognitive health after recovery from acute illness and delirium-prospective study

Acronym
ORCHARD-PS

Study objectives
The primary objective is to study multimodal biomarkers (clinical, cognitive, digital, blood, neuroimaging) associated with delirium and subsequent dementia in a consecutive cohort of older hospital patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/07/2023, South Central-Berkshire Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8233; berkshire.rec@hra.nhs.uk), ref: 23/SC/0199

Study design
Non-randomized observational cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Delirium and dementia, acute hospital illness in older people (>70 years)

Interventions
After consenting the participant, the researcher will ask the research questions and administer the thinking and memory tests and mobility assessment. This should take not more than one hour but may need to be performed over more than one researcher visit if there are treatment requirements or the participant becomes fatigued. The researcher will liaise with the ward team to arrange for research bloods to be taken alongside the bloods required as part of routine care where possible.

Clinical records would not be accessed by the research team until informed consent has been given. Additional information, including brain imaging from the patient's electronic record

required for completion of the study research questions, will be extracted by the researcher at a convenient time after the patient interview has been completed. This will only be necessary for information recorded in free text form in the EPR since information recorded in categorical or numeric form will be available as part of the data fields in the Oxford Co-morbidity, Frailty and Ageing Research Database (ORCHARD). ORCHARD contains individual EPR data on all Oxford University Hospitals patients aged >/=70 years with unplanned admission and includes information on nursing risk assessments (eg falls risk, nutrition), observations, illness severity measures, diagnoses, and mandatory cognitive assessments.

Before discharge, the researcher will arrange for a 3 month follow-up to be done in the out-patient clinic, in person at the patient's home or by telephone where this is not possible. Further follow-up visits will be planned for 1 and 3 years. At the follow-up visits, patients will be administered the study questions, and the thinking and memory tests and mobility assessments will be repeated. Research bloods will be repeated at the 3-month visit. If bloods are not done at 3-months, they can be done at a subsequent follow-up at year-one or year-three.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1.1. Delirium subtype, duration and severity measured using 4AT (Rapid test for delirium), Memorial Delirium Assessment Scale (MDAS), Confusion Assessment Method (CAM), Abbreviated Mental Test Score (AMTS), Observational Study of Arousal (OSLA), Richmond Agitation Scale at baseline
1.2. Transient cognitive impairment measured using Abbreviated Mental Test Score (AMTS), Montreal Cognitive Assessment (MoCA) at baseline and 3 months
1.3. Dementia and dementia subtype diagnosis according to the DSM-5 criteria (major neurocognitive disorder) and accepted sub-type diagnostic criteria informed by clinical assessment including cognitive and functional assessments at 3 months, 1 and 3 years
2.1. Demographics (baseline only) and health factors collected using Electronic Patient Records (EPR) at baseline, 3 months, 1 and 3 years
2.2. Acute illness severity measured using EPR at baseline
2.3. Frailty measured using Rockwood Clinical Frailty Scale at baseline, 3 months, 1 and 3 years.
2.4. Multimorbidity defined by the Charlson index at baseline, 3 months, 1 and 3 years.
2.5. Cognitive profile-participant assessment (AMTS, MoCA, OCS-plus) collected at baseline, 3 months, 1 and 3 years.
2.6. Cognitive profile- Informant assessment (Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE), 10-point Neuropsychiatric Inventory) at baseline and 3 years
3. Blood biomarkers collected at baseline and 3 months for inflammatory markers, neurodegeneration markers, genetic profile.
4. Brain imaging at baseline for global and regional atrophy, white matter changes defined using visual rating scales and semi-automated image analysis techniques.

Key secondary outcome(s))
1.1. Outcome measured using length of stay, readmission within 30-days, and mortality from electronic records and European Quality of Life Score (Euroqol) at 3 months, 1 and 3 years
1.2. Function measured using Hospital Assessment of Balance and Mobility (HABAM), Nottingham Extended Activities of Daily Living (ADL), Timed Up and Go Test (TUG) and modified

Rankin Scale (pre-morbid at baseline) at baseline, 3 months, 1 and 3 years
2. Added Value of advanced proton-counting CT brain imaging for quantifying brain atrophy and cerebrovascular disease including small vessel disease

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Adult hospital patients aged >=70 years with unplanned admission to OUHFT or RBHFT or assessed in the SDECs
2. Patient is willing and able to give informed consent for participation in the study OR Seek advice from a personal consultee (family member, friend or carer). If a personal consultee is unavailable, advice will be sought from a member of the hospital staff who is not part of the research team (professional consultee)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
70 years

Sex
All

Key exclusion criteria
1. Moribund status
2. Nursing Care home residence
3. Severe dementia with high degree of dependency e.g. bedbound

Date of first enrolment
09/08/2023

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
At the end of the study and when all results have been published the anonymised research data will be held in a secure repository for data sharing e.g. Dementia Platform UK in line with the University of Oxford and Funders Open data requirements. Data will be held according to the appropriate procedures and data sharing agreements in place and approved researchers may apply to access the data repository according to the agreed protocol.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/06/2025	16/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes