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FINE-ST: Frailty and inequality in stroke

Submission date
28/06/2021

Recruitment status
No longer recruiting

Registration date
21/03/2022

Overall study status
Completed

Last Edited
21/03/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Stroke is the commonest cause of neurological disability and death in the UK (>100,000 per year). The majority of strokes occur in the older generation (58% aged >70 years), whilst over one third (38%) occur in middle-aged adults.

Risk of TIA and stroke are increased in the older population, both age and frailty negatively impacting on outcomes. However, the influence of frailty on stroke outcomes (including physical function and cognition) is not well understood. Second, the association between death from cardiovascular disease (including stroke) and health inequality is also
stark with greater inequality associated with worse outcomes from heart attacks and strokes. It is therefore important to understand how diversity and inequality across the region relate specifically to mini-strokes (transient ischaemic attack, TIA) and strokes.

We therefore plan to identify patients assessed through the rapid access TIA clinics and stroke units in the East Midlands with the aim to explore the relationships between frailty, co-morbidity, health inequality and clinical outcomes. This information will help inform future trial design in the frail elderly population with stroke, and enable us to tailor more appropriate, potentially cost saving approaches to treatment.

Who can participate?
Patients aged over 40 years, who have had a stroke in the past 3 years

What does the study involve?
The study simply collects information through administration of a questionnaire at two time points (baseline and 90 days later) in two groups (within 6 weeks of the TIA/stroke; and >6 weeks of the TIA/stroke). The questionnaire at baseline is administered either face-to-face whilst in hospital, or sent via the post if the participant is at home. The questions asked 90 days later will be performed over the telephone.

What are the possible benefits and risks of participating?
None

Where is the study run from?
University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
November 2019 to December 2021

Who is funding the study?
National Institute for Health Research CRN East Midlands (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
273619

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 273619, CPMS 44689

Study information

Scientific Title
Frailty, Inequality and Co-morbidity: a cohort study in TIA and Stroke

Acronym
FINE-ST

Study objectives
Frailty, co-morbidity and health inequality negatively impact stroke outcomes. Understanding the relationship between frailty, multi-morbidity, inequality and outcome will inform the design of trials for current and future health care interventions in an ageing stroke population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/03/2020, HRA and Health and Care Research Wales (HCRW) (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 785738; Wales.REC1@wales.nhs.uk), ref: 20/WA/0039

Study design
Multi-centre pilot prospective population based longitudinal cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
To initiate a stroke cohort to inform the relationship between frailty, multi-morbidity, socioeconomic status and clinical outcome in TIA and stroke.

Interventions

The study simply collects information through administration of a questionnaire at two time points (baseline and 90 days later) in two groups (within 6 weeks of the TIA/stroke; and >6 weeks of the TIA/stroke). The questionnaire at baseline is administered either face-to-face whilst in hospital, or sent via the post if the participant is at home. The questions asked 90 days later will be performed over the telephone.

Intervention Type
Other

Primary outcome(s)
1. Frailty will be measured using the CFS, PRISMA 7 and FI-GCA at baseline and day 90.
2. Functional outcome will be measured using the MRS at baseline and day 90.

Key secondary outcome(s))
1. Frailty will be measured using the CFS, PRISMA 7 and FI-GCA at baseline and day 90.
2. Disability will be measured using the Barthel Index (BI) at baseline and day 90.
3. Dysphagia will be measured using the Dysphagia Severity Rating Scale (DSRS) at baseline and day 90
4. Cognition will be measured using the Montreal Cognitive Assessment (MoCA) and Telephone Mini Mental State Examination (t-MMSE) at baseline and day 90
5. Mood will be measured using the Geriatric Depression Scale (GDS) and Zung Depression Scale (ZDS) at baseline and day 90.
6. Inequality will be measured using the English Indices of Deprivation scale at baseline and day 90.
7. Fatigue will be measured using the Fatigue Assessment Scale (FAS) at baseline and day 90.
8. Co-morbidity will be measured using the Charleston Co-morbidity Index (CCI) at baseline.

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. TIA, ischaemic or haemorrhagic stroke in the last: 6 weeks (subacute group), or 6 weeks to 3 years (chronic group)
2. Age >40 years
3. Written consent from participant or proxy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Probable stroke mimic (e.g. migraine, functional neurology, brain tumour)
2. Life expectancy <3 months
3. Not expected to complete follow up at day 90 (e.g. homeless, out-of-area)
4. Level of consciousness prohibits engagement in baseline measures

Date of first enrolment
17/09/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Derby Hospital
University Hospitals of Derby and Burton NHS Foundation Trust
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Nottingham City Hospital
Nottingham University Hospitals NHS Trust Stroke Services
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR CRN East Midlands

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 1.0	11/11/2025	11/11/2025	No	Yes
Protocol file		28/11/2019	09/09/2021	No	No