ISRCTN42688361 https://doi.org/10.1186/ISRCTN42688361

Following stroke or TIA can patient screening & enhanced risk factor management prevent subsequent memory decline.

Submission date
15/04/2015

Recruitment status
No longer recruiting

Registration date
16/04/2015

Overall study status
Completed

Last Edited
21/09/2020

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Previous research indicates that many patients who have suffered from a stroke or mini-stroke (Transient Ischemic Attack [TIA]) are already showing signs of cognitive decline (problems with thinking, reasoning and remembering) at the time of diagnosis. Previous research also indicates that about a third of stroke patients who have normal cognition at diagnosis go on to develop dementia as early as 3 months after stroke. The aim of this study is to find out if the early detection of cognitive decline at the time of stroke or mini-stroke (TIA) diagnosis can prevent, slow down or even reverse the onset of dementia. The study hopes to find out if improved monitoring and control of vascular risk factors such as high blood pressure, high cholesterol, irregular heart beat (atrial fibrillation) and diabetes, can slow down cognitive decline.

Who can participate?
Adult patients with mild ischemic stroke or TIA

What does the study involve?
At the time of stroke/TIA diagnosis a simple cognitive screening test is carried out. The score the patient gets determines what part of the study they can participate in. Patients with a score of less than 20 are not able to take part in the study. Patients with a score of 26 or over are invited to participate in the observational study. Patients with a score of 20-25 are invited to participate in the feasibility study.
The goal of the observational study is to see if there is a link between vascular risk factors, control of these risk factors and cognitive function after stroke/TIA. Participants in the observational study have their vascular risk factors (e.g. high blood pressure, high cholesterol, irregular heart beat [atrial fibrillation]) and diabetes assessed at the start of the study and after 1 year.
The goal of the feasibility study is to evaluate the feasibility of conducting a hospital-based study of stroke/TIA patients who are at risk of further cognitive decline. Participants are randomly allocated to one of two groups: an intervention group and a control group.

Participants in the intervention group have targets set for each of their risk factors which are monitored by the hospital and by their GP. Participants in the control group receive standard care. The cognitive test is repeated after 6 months and 1 year.

What are the possible risks and benefits of taking part in this study?
Participants with a score of 26 or over will be reassured that they have normal cognition. Participants with a score of 20-25 who are allocated to the feasibility intervention group will have the benefit of closer and frequent monitoring of risk factors which may possibly reduce risk of a further stroke/TIA. They might also have the advantage of reducing further cognitive decline. Participants with a score of less than 20 will be referred to their GP and to appropriate services if required. Participants scoring less than 26 may experience some anxiety. Referral and support will be given. By doing so, we hope that the anxiety will be reduced.

Where is the study run from?
Norfolk and Norwich University Hospital (NNUH) (UK)

When is the study starting and how long is it expected to run for?
August 2015 to April 2017

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

Who are the main contacts?
1. Prof. John Potter
2. Prof. Phyo Myint

Contact information

Type(s)
Public

Contact name
Prof John Potter

Contact details
Norfolk and Norwich University Hospital NHS Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

18803

Study information

Scientific Title
SERVED Memory: Feasibility study of Screening & Enhanced Risk management for Vascular Event related Decline in Memory

Acronym
SERVED Memory

Study objectives
This study sets out to assess if the early detection of cognitive decline (memory problems) following a recent stroke or transient ischaemic attack (TIA or ministroke) can be prevented, slowed down or potentially reversed by addressing vascular risk factors (VRF) more intensively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
15/EE/0061

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Stroke; Subtopic: Prevention; Disease: Therapy type

Interventions
In both study groups at the start of the study and after 12 months a 24 hour blood pressure recording will be taken.

At the start of the study and after 12 months pulse wave velocity (PWV) measurements will be made to examine the stiffness of the participants arteries.

Participants with an irregular heart rhythm (atrial fibrillation) will have 10 minute beat to beat variation in blood pressure measurements recorded using a Taskforce monitor at the start of the study and at 12 months.

Participants assigned to the Intervention group will be given risk factor targets which will be re-assessed at 3, 6, 9 and 12 months by the research team. If participants are not reaching their target levels, their GP will be informed.

Participants from all study groups will be asked to complete a health-related quality of life questionnaire (called EQ-5D), a dementia-specific quality of life questionnaire (called DEMQOL), a geriatric depression scale questionnaire (called GDS) and a resource use cost questionnaire at baseline and 12 months. At the end of the study, participants will also be asked to complete the Bristol Activities of Daily Living Scale and the study team will carry out a short questionnaire that is used for the diagnosis of vascular dementia (Hachinski Test).

Intervention Type
Procedure/Surgery

Primary outcome measure
Changes in Cognition and in CV risk factors over 1 year follow-up; Timepoint(s): Changes in Cognition and in CV risk factors over 1 year follow-up

Secondary outcome measures
N/A

Overall study start date
01/08/2015

Completion date
31/12/2018

Eligibility

Key inclusion criteria
All adult patients admitted to the participating centre with confirmed stroke (first/recurrent) or TIA will be considered for the trial.
Inclusion criteria
1. Normal cognition (MoCA score >=26) and no evidence of moderate/severe depression (GDS <9). Patients with normal cognition (MoCA score >=26) will be informed of their normal cognition status and will be managed routinely by the clinicians with regards to their risk factors. They will be invited to participate in the observational study (defined as GROUP O). If they agree, written informed consent will be obtained.
2. Intermediate cognition (MoCA score 20-25). Patients with MoCA score of 20-25 will be informed of their cognitive status and be invited to participate in the feasibility trial. Those who agree and provide written informed consent will be randomised into one of two groups; control arm (GROUP C) and intervention arm (GROUP I).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment
167

Key exclusion criteria
Those with following conditions will be excluded on ethical grounds:
1. Severe cognitive deficit (MoCA <20). Patients with severe cognitive deficit (MoCA <20) will be informed of their cognition status and their GP will also be informed for further appropriate action. Hospital teams will be liaised with and an appropriate level of community support at discharge will be organised. By doing so, we hope that the anxiety of knowing their cognitive deficit will be reduced. They will be excluded from the trial as it is not ethical to include them in the feasibility stage.
2. Established Dementia / MoCA score <20
3. Moderate/severe depression
4. Life expectancy <1 yr (e.g. severe stroke/terminal cancer)
5. Unable to perform MoCA (aphasic patients)

Date of first enrolment
01/08/2015

Date of final enrolment
01/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Norfolk and Norwich University Hospital NHS Trust
Colney Lane,
Colney
Norwich, Norfolk
United Kingdom
NR4 7UY

Sponsor information

Organisation
Norfolk and Norwich University Hospital NHS Trust

Sponsor details
Colney Lane
Colney
Norwich
England
United Kingdom
NR4 7UY

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01wspv808

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/09/2020	21/09/2020	Yes	No
HRA research summary			28/06/2023	No	No