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Study of brain and leg muscle characteristics identified using magnetic resonance imaging (MRI) to predict the likelihood of leg function recovery following stroke

Submission date
12/03/2020

Recruitment status
No longer recruiting

Registration date
22/04/2020

Overall study status
Completed

Last Edited
10/11/2023

Condition category
Circulatory System

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

Plain English summary of protocol

A common consequence of ischaemic stroke is the loss of lower limb function. This can lead to a stoke survivor being unable to continue to live an independent life. It would be beneficial to stroke survivors if clinicians could accurately predict recovery of lower limb function. An accurate prognosis would also enable treatment plans such as the content and duration of rehabilitation to be optimised. However, at present there is a lack of reliable methods for predicting recovery of movement after stroke. Advanced magnetic resonance imaging (MRI) imaging can demonstrate the effect of stroke on the nerve pathways in the brain and the changes in the affected muscles in great detail. Advanced MRI has shown early promise in making recovery predictions in small-scale studies. Our research aims to build on this evidence and answer the question of whether advanced MRI can be used to predict how well stroke survivors will recover lower limb function.

We aim to study 30 participants who have had a first ever ischaemic stroke within the previous four weeks causing different degrees of stroke severity affecting the lower limb. They will undergo MRI brain and lower limb muscle scans lasting 50-60 minutes in a dedicated MRI facility in Newcastle University's Campus for Ageing and Vitality. A test of physical strength and functional ability of the affected leg lasting about 30mins will be done around the time of the MRI scan and repeated 3 months after stroke. Analysis of our findings will determine whether advanced MRI scan findings are linked to the stroke survivors' recovery of limb function.

Background and study aims
A common consequence of ischaemic stroke is the loss of lower limb function. This can lead to a stoke survivor being unable to continue to live an independent life. It would be beneficial to stroke survivors if clinicians could accurately predict recovery of lower limb function. An accurate prognosis would also enable treatment plans such as the content and duration of rehabilitation to be optimised. However, at present there is a lack of reliable methods for predicting recovery of movement after stroke. Advanced magnetic resonance imaging (MRI) imaging can demonstrate the effect of stroke on the nerve pathways in the brain and the

changes in the affected muscles in great detail. Advanced MRI has shown early promise in making recovery predictions in small-scale studies. This research aims to build on this evidence and answer the question of whether advanced MRI can be used to predict how well stroke survivors will recover. The aim is to study 30 participants who have had a first-ever ischaemic stroke within the previous 4 weeks causing different degrees of stroke severity affecting the lower limb. Analysis of our findings will determine whether advanced MRI scan findings are linked to the stroke survivors' recovery of limb function.

Who can participate?
Patients aged 18 or over from study centres with first-ever acute ischaemic stroke who meet the eligibility criteria

What does the study involve?
Patients will undergo MRI brain and lower limb muscle scans lasting 50-60 minutes in a dedicated MRI facility in Newcastle University's Campus for Ageing and Vitality. A test of physical strength and functional ability of the affected leg lasting about 30 minutes will be done around the time of the MRI scan and repeated 3 months after stroke.

What are the possible benefits and risks of participating?
There are no possible benefits or risks associated with participation in the study.

Where is the study run from?
The study is run from Newcastle University and involves hospital sites from Northumbria Healthcare and Newcastle upon Tyne Hospitals NHS Foundation Trusts (UK)

When is the study starting and how long is it expected to run for?
January 2017 to August 2022

Who is funding the study?
NIHR Newcastle Biomedical Research Centre (UK)

Who is the main contact?
Miss Hannah Lumley
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
249942

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
8656, IRAS 249942

Study information

Scientific Title
Study In NOvel Neuro-muscular Imaging biomarkers for Motor outcome in Stroke (SINONIMS)

Acronym
SINONIMS

Study objectives

Hypothesis A: Sarcopenia and loss of motor impairment will be most pronounced in those patients whose ischaemic stroke causes greatest damage to the cortico-spinal (CS) tract and motor pathways as determined by advanced neuroimaging.

Hypothesis B: A combination of imaging biomarkers of loss of connectivity in brain and sarcopenia will increase the ability to predict motor outcome in stroke when compared to individual biomarkers alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/03/2019, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224558458; nosres@nhs.net), ref: 19/NS/0036

Study design
Observational longitudinal cohort study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Acute ischaemic stroke

Interventions
30 acute ischaemic stroke patients with varying degrees of lower limb weakness will undergo advanced magnetic resonance imaging of the brain and thigh muscles, followed by assessments of baseline lower limb motor function (within 4 weeks of onset). A follow-up clinical assessment at 3 months post ictus will then be conducted. The researchers will then examine the relationships between imaging biomarkers and motor outcome in view of developing a predictive model for more accurate prognosis of lower limb motor recovery. This is a small pilot study which is unlikely to result in a robust predictive model; however, it will inform future multicentre studies by exploring feasibility and providing means by which to perform a sample size calculation. In future, this could improve the efficiency of rehabilitation - tailored to the needs of the individual based on their prognosis.

Intervention Type

Other

Primary outcome measure
Lower limb functional impairment measured using the Fugl Meyer Lower Limb Assessment at baseline and 3 months post stroke

Secondary outcome measures
Measured at baseline and 3 months post stroke:
1. Leg muscle strength measured using lower limb dynamometry
2. Severity of functional impairment measured using the Lower Limb component of the National Institute of Health Stroke Scale
3. Walking ability measured using the Functional Ambulation Category scale

Overall study start date
01/01/2017

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Adults aged 18 or over with first-ever unilateral supra-tentorial ischaemic stroke
2. Unilateral lower limb motor deficit +/- upper limb motor deficit
3. Less than 4 weeks after stroke onset

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
47

Key exclusion criteria
1. Absolute contra-indication to MRI (e.g. pacemaker)
2. Posterior circulation or haemorrhagic stroke (haemorrhagic transformation of ischaemic stroke is not considered as an exclusion criterion)
3. Previous history of anterior circulation stroke (clinically or radiologically) or posterior circulation stroke with residual clinical deficit

4. Lack of capacity to provide informed consent
5. Unable to transfer independently or with assistance of one person if scanned in Newcastle University or with assistance of two people if scanned in Royal Victoria Infirmary
6. Unable to answer MRI safety questionnaire
7. Moderate to high level of dependency prior to stroke (modified Rankin score of >2)
8. Any other pre-existing co-morbidity causing a significant lower limb deficit

Date of first enrolment
15/07/2019

Date of final enrolment
01/04/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbria Way
Cramlington
United Kingdom
NE23 6NZ

Study participating centre
Wansbeck General Hospital
Woodhorn Lane
Ashington
United Kingdom
NE63 9JJ

Study participating centre
North Tyneside General Hospital
Rake Lane
Tyne and Wear
North Shields
United Kingdom
NE29 8NH

Study participating centre

Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Newcastle Joint Research Office
Level 1, Regent Point
Regent Farm Road
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Newcastle upon Tyne
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NE3 3HD
+44 (0)191 2824461
nuth.nuthsponsorship@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
NIHR Newcastle Biomedical Research Centre

Alternative Name(s)
Newcastle Biomedical Research Centre, Newcastle NIHR Biomedical Research Centre

Funding Body Type

Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Protocol available on request. The researchers are intending to publish the final results.

Intention to publish date
31/07/2023

Individual participant data (IPD) sharing plan
The researchers are planning to store raw imaging data (T1; T2; DWI and DTI of brain, T1; STIR; MR Spectroscopy and 3-point Dixon of thigh muscles) alongside the clinical assessment data in the ENIGMA consortium (http://enigma.ini.usc.edu/about-2/).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.4	18/05/2021	25/07/2023	No	No
HRA research summary			26/07/2023	No	No
Results article		24/10/2023	10/11/2023	Yes	No