

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

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<b>Registration date</b> 22/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/11/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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 stroke 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 stroke 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

**Contact name**

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
249942

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

### **Study type(s)**

Diagnostic

### **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(s)**

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

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

United Kingdom

England

## 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

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

**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?
<a href="#">Results article</a>		24/10/2023	10/11/2023	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Protocol file</a>	version 1.4	18/05/2021	25/07/2023	No	No