

# Standardised stroke risk assessment for patients with migraineous symptoms reviewed as suspected TIA (transient ischemic attack)

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
20/10/2024	Recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
13/11/2024	Ongoing	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
06/01/2026	Nervous System Diseases	<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Transient ischemic attack (TIA), also known as a mini-stroke, is a common event during which people briefly experience stroke symptoms including loss of movement, sensation, speech and vision. There is a risk of permanent stroke during the next 90 days which can be reduced by urgent medical treatment. However, being certain of the diagnosis is challenging because other conditions can produce identical symptoms. The commonest condition which can produce the same symptoms is migraine, and people suffering migraine are not at high risk of stroke. Tests have a limited role in differentiation between TIA and migraine and uncertainty about the correct diagnosis can lead to missed opportunities to prevent stroke if TIA is not recognised, and overtreatment of people with migraine.

This research study aims to develop an assessment which will help clinicians predict the risk of stroke when reviewing patients presenting with symptoms which could be caused by both TIA and migraine.

### Who can participate?

Adults (aged 40 years and over) who present with symptoms which could be caused by both TIA and migraine.

### What does the study involve?

Clinical information will be collected from people who agree to take part. This will include presenting symptoms, investigations and treatments, and what happens to health over the next 90 days. This information will be analysed mathematically to develop the stroke risk assessment.

### What are the possible benefits and risks of participating?

There are no direct benefits to individuals who take part in the study, but it is hoped that care for future patients will be improved as a result of this research.

### Where is the study run from?

Newcastle University (UK)

When is the study starting and how long is it expected to run for?  
August 2024 to July 2027

Who is funding the study?  
NIHR Research for Patient Benefit Programme (UK)

Who is the main contact?  
Jemma Isaac, [jemma.isaac@newcastle.ac.uk](mailto:jemma.isaac@newcastle.ac.uk)

## Contact information

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Public, Scientific

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## Additional identifiers

**Integrated Research Application System (IRAS)**  
318870

**Central Portfolio Management System (CPMS)**  
53619

## Study information

**Scientific Title**

Standardised stroke risk assessment for patients with Migrainous symptoms Reviewed as suspected TIA

**Acronym**

SMART

**Study objectives**

The aim of the study is to define the risk of stroke for people with migrainous symptoms reviewed as suspected transient ischemic attack (TIA) and develop a stroke risk assessment tool that could promote standardisation of care.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 11/09/2024, London - Stanmore Research Ethics Committee (2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 1048258; stanmore.rec@hra.nhs.uk), ref: 24/PR/0977

**Study design**

Observational cohort study

**Primary study design**

Observational

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

Suspected TIA or migraine.

**Interventions**

This research project is an observational cohort study involving patients with symptoms which could be caused by both TIA and migraine. At study entry, data will be collected about presenting symptoms, investigations and treatments. After 90 days, data will be collected about further episodes of migraine or TIA, and whether a stroke has occurred.

**Intervention Type**

Other

**Primary outcome(s)**

Stroke occurrence determined from medical record information and independent adjudication at 90 days

**Key secondary outcome(s)**

Clinical features, investigations and treatments determined from medical record information at baseline

**Completion date**

31/07/2027

## Eligibility

### Key inclusion criteria

1. Adults with migrainous symptoms reviewed as suspected TIA by a TIA/stroke service
2. Initial review conducted within 1 week of last symptoms
3. Following initial review, a specialist clinician symptom-based diagnosis is either possible migraine or possible TIA with migrainous symptoms
4. At least 40 years old
5. Able to provide informed research consent

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Mixed

### Lower age limit

40 years

### Upper age limit

99 years

### Sex

All

### Total final enrolment

0

### Key exclusion criteria

1. Suspected/confirmed TIA without any migrainous features
2. Clear alternative diagnoses after initial review (e.g., seizures)
3. Previous stroke
4. Referral already made or planned for surgical intervention to prevent stroke (e.g., carotid endarterectomy or atrial septal defect closure)
5. Currently under secondary care review for the same neurological symptoms
6. Cognitive difficulties preventing consent and/or description of subjective symptoms
7. Life expectancy <90 days
8. Study day 90 follow-up is not possible (e.g., resident outside of the service boundary)

### Date of first enrolment

18/11/2024

### Date of final enrolment

30/11/2026

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

**Northumbria Healthcare NHS Foundation Trust**

North Tyneside General Hospital

Rake Lane

North Shields

Newcastle upon Tyne

England

NE29 8NH

# Sponsor information

## Organisation

Northumbria Healthcare NHS Foundation Trust

## ROR

<https://ror.org/01gfeyd95>

# Funder(s)

## Funder type

Government

## Funder Name

Research for Patient Benefit Programme

## Alternative Name(s)

NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

[lisa.shaw@newcastle.ac.uk](mailto:lisa.shaw@newcastle.ac.uk)

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#"><u>Protocol article</u></a>		24/12/2025	06/01/2026	Yes	No