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

Submission date
20/10/2024

Recruitment status
Recruiting

Registration date
13/11/2024

Overall study status
Ongoing

Last Edited
12/11/2025

Condition category
Nervous System Diseases

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

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Public, Scientific

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Public, Principal investigator

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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

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes