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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
13/11/2024

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

Type(s)
Public, Scientific

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Public, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
318870

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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

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

Overall study start date
01/08/2024

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

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants
2709

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
England

United Kingdom

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
Newcastle upon Tyne
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NE29 8NH

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details
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peta.heslop@northumbria-healthcare.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.northumbria.nhs.uk/

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, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date