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The UK Young Stroke study exploring the demographics, risk factors, investigation and outcomes of ischaemic and haemorrhagic strokes in patients aged 18-49 years old in the UK

Submission date 04/09/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 23/09/2025	**Overall study status** Ongoing	[X] Statistical analysis plan [_] Results
Last Edited 25/09/2025	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Worldwide, 15 million people suffer a stroke annually. Approximately 10-15% occur in 'young' patients (18-50 years old). Stroke rates are decreasing in the elderly but are increasing in the young. Young patients commonly share the same risk factors that were considered to be encountered solely in elderly persons. There is very little evidence on how best to investigate and treat young stroke patients. People who have a stroke when young are very likely to need physical and psychological support even years after their stroke, and anxiety, depression, and fatigue are all extremely common. A third of patients have not returned to work one year after their stroke. Recurrence of stroke or another blood vessel problem elsewhere in the body can occur in a third of patients 15 years after a young stroke. The long-term risk of death is higher in a young person who has had a stroke compared to someone of the same age who has not had a stroke.

In the UK, there are over 100,000 strokes annually. An estimated 10,000 of these cases will be young. Young strokes are increasing in the UK. Physical and psychological disability after a stroke is high and often leads to role reversal in a household, with the spouse or children acting as carers, a situation that can cause immense stress for the entire family. Inability to maintain employment affects personal finances, and there are costs to society of supporting dependent patients long-term. Previous young stroke studies based in Europe include minimal input from the UK and involve purely white European populations. This needs a better understanding of young strokes. It is particularly important in the UK with its multi-ethnic and multi-cultural population and will enable the development of targeted public health interventions, screening of high-risk groups and improved training and awareness of health care professionals. The United Kingdom Young Stroke Study (UKYSS) is a multi-centre study that aims to uncover the

factors behind young strokes, the outcomes of patients and the reasons behind those outcomes to create a model that will allow the prediction of who may develop certain problems after a young stroke.

Who can participate?
People aged over 18 and under 50 who have had either their first ischaemic stroke confirmed by imaging or clinical symptoms, or a haemorrhagic stroke confirmed by a brain scan.

What does the study involve?
Patients will be identified by individual stroke units using their entries into the national audit of strokes. Anonymised, routinely collected data about young stroke patients will be obtained and analysed. Patients will also be invited to complete a life after stroke questionnaire to understand the common problems young stroke patients encounter after their stroke.

A simplified version of the findings will be disseminated to participants who have indicated they would like to receive it on the consent form. This will also be sent to patient organisations, not limited to the Stroke Association and Different Strokes. It will also be sent to local media outlets, which are relevant to the local population and local policy makers, with the hope of informing public health policy.

What are the possible benefits and risks of participating?
No benefits and risks given at registration

Where is the study run from?
Keele University, UK

When is the study starting and how long is it expected to run for?
June 2023 to December 2025

Who is funding the study?
Keele University, UK

Who is the main contact?
Dr Phillip Ferdinand (Chief Investigator), phillip.ferdinand@uhnm.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
321270

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Protocol number RG-0349-22

Study information

Scientific Title
The United Kingdom Young Stroke Study (UKYSS)

Acronym
UKYSS

Study objectives
Primary Objective:
To create a prediction model for ischaemic stroke recurrence and haemorrhagic stroke mortality in young stroke patients.

Secondary Objectives
1. Identification and recruitment of patients from multiple stroke centres around the UK.
2. To understand the interaction between age, sex and ethnicity with risk factors, investigations and outcomes listed above.
3. To identify risk factors relating to stroke (and other vascular) recurrence, morbidity, and mortality.
4. To identify the effect of stroke on life satisfaction and the ability to fulfil a role in society.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/05/2023, South Central - Berkshire Research Ethics Committee (Bristol REC Centre, Temple Quay House, 2 The Square, Temple Quay , Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8178; berkshire.rec@hra.nhs.uk), ref: 23/SC/0145

Study design
Ambispective observational study

Primary study design

Observational

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Stroke in the young adult (>18 and <50 years old)

Interventions
Potential participants (or, where necessary, a personal consultee) will be contacted by telephone by the participating site and the study explained. Interested participants will be sent a web link for completion of an online consent form. On completion of consent, a life after stroke questionnaire will appear on the same link for participants to complete. Alternative methods (paper, text messaging) of consenting/questionnaire completion can be provided at the patient's request. In circumstances when a patient cannot be contacted or they do not wish to take part in the life after stroke part of the study, ethical approval is in place for participating sites to submit anonymised patient clinical data on the baseline and post-stroke parts of the case report form, as this is routinely collected clinical data. No newly generated information will be collected without consent.

Intervention Type
Other

Primary outcome(s)
The creation of a prediction model for ischaemic stroke recurrence and haemorrhagic stroke mortality in young stroke patients assessed through data collection on stroke recurrence and mortality, and measured using a multivariable prognostic model that will be internally and externally validated - timing will be based on median follow-up, the aim is for 5 years

Key secondary outcome(s))
1. Number and characteristics of patients successfully identified and recruited from multiple stroke centres across the UK, assessed through data collection on demographics and stroke, imaging and risk factor characteristics measured using descriptive statistics at baseline
2. Interaction effects between age, sex, and ethnicity on stroke-related risk factors, diagnostic investigations, and clinical outcomes measured using Chi-squared and Fisher Exact tests (if values <5) to compare categorical variables across groups. The Student t test will be used to compare means between groups, with the Mann-Whitney in instances where the data is not normally distributed at baseline
3. Recurrence, morbidity, and mortality due to stroke (or other vascular) specific risk factors assessed through data collection on time to recurrent stroke or other vascuar event, seizure and malignancy via creation of Kaplain Meier survival curves to measure cumulative incidences and fitting of cox regression models and hazard ratios calculated to estimate prognositc value of individual factors]; the timepoint is retrospective (2013-2020) and done at the point of contact so the reported time will be a mean follow up
4. Changes in life satisfaction and perceived ability to fulfil societal roles following stroke measured using the Fatigue Severity Scale and Stroke Impact Scale; the timepoint is retrospective (2013-2020) and done at the point of contact, so the reported time will be a mean follow-up

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Aged >18 and under 50 years old
PLUS one of the following:
1.1. For the first-ever ischaemic stroke, defined as:
1.1.1. Imaging positive (CT or MRI) acute ischaemic lesion.
The lesion must correlate with clinical presentation OR
1.1.2. Clinical symptoms with appropriate changes on CT perfusion scanning that may subsequently reverse post appropriate treatment OR
1.1.3. Symptoms lasting less than 24 hours but with evidence of acute ischaemic change on imaging that matched clinical symptoms.
1.2. For haemorrhagic stroke:
1.2.1. Evidence of acute parenchymal intracerebral haemorrhage on CT/MRI imaging

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
49 years

Sex
All

Key exclusion criteria
Exclusion Criteria
- previous stroke
- sub dural, extra-dural or sub-arachnoid haemorrhage (unless primary presentation is ICH)
- Stroke secondary to trauma
- post surgical stroke
- retinal artery occlusion
- cerebral venous thrombosis (unless primary presentation is ICH)

Date of first enrolment
09/01/2024

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
Mid Cheshire Hospitals NHS Foundation Trust
Leighton Hospital
Leighton
Crewe
United Kingdom
CW1 4QJ

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
The Shrewsbury and Telford Hospital NHS Trust
Mytton Oak Road
Shrewsbury

United Kingdom
SY3 8XQ

Study participating centre
Sandwell and West Birmingham Hospitals NHS Trust
Midland Metropolitan University Hospital
Grove Lane
Smethwick
United Kingdom
B66 2QT

Sponsor information

Organisation
Keele University

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
University/education

Funder Name
Keele University

Alternative Name(s)
La Universidad de Keele

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Phillip Ferdinand (Chief Investigator), phillip.ferdinand@uhnm.nhs.uk.

• The type of data that will be shared - will add later
• Timing for availability - currently unknown, will add later
• Whether consent from participants was required and obtained - consent not required for routinely collected data, consent obtained for life after stroke data
• Comments on data anonymization - data is already in anonymized format
• Any ethical or legal restrictions - any sharing will be subject to agreement between the sponsor and the relevant organisation and relevant local and/or national data sharing legislation
• Any additional comments - nil

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2	20/06/2023	23/09/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	version 1.3	08/07/2025	23/09/2025	No	No