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Stroke at younger ages

Submission date 22/01/2024	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 01/02/2024	**Overall study status** Ongoing	
Last Edited 06/06/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
We have seen a doubling in the number of new stroke cases in adults under the age of 55 years in the last 10 years in the UK and in other high-income countries. However, the reasons for this increase remain unclear. The aim of this study is to find out how traditional stroke risk factors that are more common at older ages, such as high blood pressure, diabetes, high cholesterol level, smoking and obesity, might contribute to the occurrence of stroke at younger ages. The researchers are also hoping to find out if emerging stroke risk factors also play a role in the rising number of young stroke cases, such as long working hours, stress and mental health conditions.

Who can participate?
Adult patients aged between 18-54 years with diagnosed stroke

What does the study involve?
The study will involve a short questionnaire (about 30 minutes) through an interview with the local study team, where they will collect information on participants' past medical history, lifestyle-related factors, family history, birth history, and other stroke risk factors. The research team will also collect relevant information about the stroke episode. The interview can be done face-to-face during the hospital stay or by phone after participants are discharged. All patients will undergo centralised administrative follow-up via record linkage for up to 30 years.

What are the possible benefits and risks of participating?
The study only includes a short questionnaire and there are no unlikely foreseeable risks associated.

Where is the study run from?
Oxford University (UK)

When is the study starting and how long is it expected to run for?
October 2023 to December 2056

Who is funding the study?
1. Oxford University (UK)
2. Oxford BRC (UK)
3. Wellcome Trust (UK)

Who is the main contact?
Dr Linxin Li, linxin.li@ndcn.ox.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
328197

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 328197

Study information

Scientific Title
National Young Stroke Study

Acronym

NYSS

Study objectives
The primary objectives of this study are to provide up-to-date and reliable estimates of the associations of traditional modifiable risk factors and emerging risk factors and young stroke.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/01/2024, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8278; gmsouth.rec@hra.nhs.uk), ref: 24/NW/0003

Study design
Prospective cohort study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Prevention, Quality of life

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
Stroke

Interventions
The study will involve a short questionnaire (about 30 minutes) through an interview with the local study team, where they will collect information on participants' past medical history, lifestyle-related factors, family history, birth history, and other stroke risk factors. The research team will also collect relevant information about the stroke episode. The interview can be done face-to-face during the hospital stay or by phone after participants are discharged. All patients will undergo centralised administrative follow-up via record linkage for up to 30 years.

Intervention Type
Other

Primary outcome measure
1. Traditional vascular risk factors (e.g. hypertension, diabetes, hyperlipidaemia, obesity, smoking, alcohol excess) measured using questionnaire/medical records at baseline
2. Emerging risk factors (e.g. depression, anxiety and other mental health conditions, long

working hours, stress, autoimmune conditions, oral health) measured using questionnaire /medical records at baseline

Secondary outcome measures
1. Long-term vascular (recurrent stroke, myocardial infarction, dementia and vascular death) and non-vascular outcomes (cancer and mental health conditions) measured using medical record linkage at 5, 10, 20 and 30 years
2. Stroke severity measured using National Institutes of Health Stroke Scale (NIHSS) at baseline
3. Disability measured using modified Rankin scale at baseline in the first instance
4. Quality of life measured using EQ-5D at baseline in the first instance

Overall study start date
01/10/2023

Completion date
31/12/2056

Eligibility

Key inclusion criteria
1. Patient is willing and able to give informed consent for participation in the study, or favourable consultee advice for adults lacking capacity
OR
If consent or consultee advice was not feasible, CAG/Section 251 support for data collection
2. Male or Female, aged 18 to 54 years
3. A diagnosis of ischaemic stroke (including retinal artery occlusion)
OR
A diagnosis of intracerebral haemorrhage

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
54 Years

Sex
Both

Target number of participants
2000

Key exclusion criteria
1. Intracerebral haemorrhage as a result of trauma
2. Ischaemic stroke or intracerebral haemorrhage as a result of cerebral venous thrombosis

Date of first enrolment
01/10/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Thames Valley & South Midlands CRN
United Kingdom
N/A

Study participating centre
North East and North Cumbria CRN
United Kingdom
N/A

Study participating centre
North West Coast CRN
United Kingdom
N/A

Study participating centre
Yorkshire and Humber CRN
United Kingdom
N/A

Study participating centre
Greater Manchester CRN
United Kingdom
N/A

Study participating centre
East Midlands CRN
United Kingdom
N/A

Study participating centre
West Midlands CRN
United Kingdom
N/A

Study participating centre
West of England CRN
United Kingdom
N/A

Study participating centre
East of England CRN
United Kingdom
N/A

Study participating centre
Kent, Surrey and Sussex CRN
United Kingdom
N/A

Study participating centre
Wessex CRN
United Kingdom
N/A

Study participating centre
South West Peninsula CRN
United Kingdom
N/A

Study participating centre

North Thames CRN
United Kingdom
N/A

Study participating centre
South London CRN
United Kingdom
N/A

Study participating centre
North West London CRN
United Kingdom
N/A

Study participating centre
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Sponsor information

Organisation
University of Oxford

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Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
University/education

Funder Name
University of Oxford

Alternative Name(s)
St Cross College, University of Oxford

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/12/2029

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

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