Stroke at younger ages

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

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

 Traditional vascular risk factors (e.g. hypertension, diabetes, hyperlipidaemia, obesity, smoking, alcohol excess) measured using questionnaire/medical records at baseline
 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 Wolfson Centre for Prevention of Stroke and Dementia, NDCN, Oxford University Wolfson Building John Radcliffe Hospital Oxford United Kingdom OX3 9DU

Sponsor information

Organisation University of Oxford

Sponsor details

Research Governance, Ethics and Assurance Boundary Brook House Churchill Drive Oxford England United Kingdom OX3 7GB +44 (0)1865-289885 RGEA.Sponsor@admin.ox.ac.uk

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