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Risk of Aneurysm Rupture (ROAR) Study: measuring the rupture risk of unruptured intracranial aneurysms in the UK

Submission date 07/04/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 21/04/2021	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 30/09/2025	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

An aneurysm is a bulge in a blood vessel due to a weakness in its wall. They are common and 3% of people have them in the brain. They can burst and cause bleeding which frequently leaves people dead or disabled. Bleeding can be prevented by procedures to treat the aneurysm. However, these procedures can cause serious complications such as stroke. They should therefore only be performed in patients whose risk of bleeding is higher than the risk of complications from the procedures.

The problem is that we are not sure exactly what the risk of bleeding from an aneurysm is. The best estimates come from the previously published PHASES study. This proposed a score based on six items, like patient age and aneurysm size, to estimate the risk of a brain aneurysm bleeding over the next 5 years. However, the PHASES score has several design flaws and neurosurgeons are unsure how accurate it is. For example, 4 out of 5 patients in the study were either Finnish or Japanese, who are the two populations in the world postulated to have a higher risk of rupture than other populations. It is therefore not possible to be sure if this applies to patients in the UK. Researchers therefore want to study a large number of patients with aneurysms that have not burst, who are also neither Finnish nor Japanese, to see which ones go on to burst and bleed.

The first aim of this study is therefore to determine whether or not the PHASES score is accurate in a UK population. Its second aim is to see if using more detail about individual patients and their aneurysms results in more accurate personalised risk estimates. The third aim of the study is to assess whether the short-term risk estimates from PHASES (which in 80% of cases come from the first year after diagnosis) are applicable to the remainder of a patient's lifetime. Answers to these questions will be of huge benefit by aiding decision making for patients with aneurysms and protect them from the harm of over- or under-treatment.

Who can participate?

Patients aged over 18 years with an unruptured intracranial aneurysm diagnosed between 2006 and 2020. As this study is being conducted using pre-existing medical records it does not require any patients to actively participate in the study.

What does the study involve?
The researchers will identify eligible patients from neurosurgical units throughout the UK and collect details, such as their demographics, relevant medical history and aneurysm size and location, from local hospital records. They will then search all of these patients against national databases for hospitals admissions (and deaths) in England, Wales and Scotland to see which patients went on to have a bleed from their aneurysm. All of the data collection, both the hospital records and databases for hospital admissions, is from medical records which already exist. Once the rupture events occurring after diagnosis have been identified, the researchers will build predictive models for aneurysm rupture risk.

What are the possible benefits and risks of participating?
Because the data is retrospective and patients will not be actively participating, there are no direct benefits or risks to the patients involved. The use of a patients' medical records will not influence the neurosurgical care they have already received. The results from this study, including a better understanding of predicting rupture risk, may change the way that unruptured aneurysms are managed in the UK. This may benefit patients in the future if their previous estimates of rupture risk are inaccurate.

Where is the study run from?
University Hospitals Southampton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2018 to July 2034

Who is funding the study?
1. Medical Research Council (MRC) (UK)
2. National Institute for Health and Care Research (NIHR) (UK)
3. Smile for Wessex (UK)
4. Polycystic Kidney Disease Charity (UK)
5. Royal College of Surgeons (UK)

Who is the main contact?
Prof. Diederik Bulters
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Study website
https://www.roarstudy.co.uk

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
276144

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 276144

Study information

Scientific Title
A UK multicentre long-term longitudinal study of unruptured intracranial aneurysms: the Risk of Aneurysm Rupture (ROAR) Study

Acronym
ROAR

Study objectives

Aim 1: To validate the PHASES score in a UK population.
Aim 2: To develop a new prediction model including additional predictors of risk.
Aim 3: To report the long-term risk of aneurysm rupture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/03/2021, South Central Hampshire A Research Ethics Committee (Temple Quay House, 2 The Square, Bristol Research Ethics Committee Centre, BS1 6PN, UK; +44 (0)207 104 8196; hampshirea.rec@hra.nhs.uk), REC ref: 21/SC/0064

Study design
Multicentre retrospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Unruptured intracranial aneurysms

Interventions
A cohort of patients with unruptured intracranial aneurysms identified by searches of scan reports, clinic letters and multi-disciplinary team (MDT) outcomes at neurosurgical units in the United Kingdom. Baseline patient and aneurysm characteristics will be collected from their hospital records. Events of aneurysm rupture on follow up will be established by linking this cohort of patients to national databases for hospital admissions (Hospital Episodes Statistics [HES]/Patient Episode Data Wales [PEDW]/Scottish Morbidity Database [SMD]) and deaths (Office of National Statistics [ONS]/National Registry Scotland [NRS]).

Added 30/09/2025: In addition to baseline data collection, imaging data will be securely transferred, anonymised and stored prior to subsequent analysis. Participants will also be approached and consented for saliva sampling to collect DNA for whole genome sequencing.

From this, observed rupture rates will be produced and compared to those estimated for this cohort by the PHASES score.

Intervention Type

Other

Primary outcome measure
Rupture of a previously diagnosed unruptured intra-cranial aneurysm demonstrated on CT imaging or sections 1a-c on a death certificate after aneurysm diagnosis

Secondary outcome measures
Growth of an unruptured intracranial aneurysm demonstrated on angiographic imaging after diagnosis

Overall study start date
01/08/2018

Completion date
31/07/2034

Eligibility

Key inclusion criteria
1. Intracranial intradural unruptured aneurysm, confirmed on angiogram (Computed Tomography Angiogram [CTA], Magnetic Resonance Angiography [MRA], Digital Subtraction Angiography [DSA])
2. Diagnosis of Unruptured Intracranial Aneurysm [UIA] between January 2006-December 2020.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20,000

Total final enrolment
20318

Key exclusion criteria
1. Mycotic or vasculitic aneurysms
2. Aneurysm diagnosed on computed tomography (CT) or magnetic resonance imaging (MRI) alone
3. Arteriovenous malformation (AVM) associated flow aneurysms
4. Extradural aneurysms (e.g. intra-cavernous)
5. Aneurysms previously treated by either microsurgical or endovascular techniques
6. Small lesions uncertain as to whether they are truly aneurysmal (“dilatation”, “bulge”, ‘Infundibulum”)

Date of first enrolment

01/05/2020

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Southampton General Hospital
University Hospitals Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
King's College Hospital NHS Trust
King's College Hospital NHS Trust
Denmark Hill
Brixton
London
United Kingdom
SE5 9RS

Study participating centre
National Hospital for Neurology and Neurosurgery
Queen Square
Holborn
London
United Kingdom
WC1N 3BG

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Road

Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospital of Wales
Cardiff and Vale University Health Board
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Hills Rd
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
University Hospitals Plymouth NHS Trust
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane

Salford
United Kingdom
M6 8HD

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham

United Kingdom
NG7 2UH

Study participating centre
The Walton Centre NHS Foundation Trust
Lower Lane
Fazakerley
Liverpool
United Kingdom
L9 7LJ

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
United Leeds Teaching Hospitals NHS Trust
Trust Offices
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Barking, Havering and Redbridge University Hospitals NHS Trust
Queens Hospital
Rom Valley Way
Romford
United Kingdom
RM7 0AG

Study participating centre
St George's University Hospitals NHS Foundation Trust
Blackshaw Road
Tooting

London
United Kingdom
SW17 0QT

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

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sharon.davies-dear@uhs.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhs.nhs.uk/home.aspx

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Smile for Wessex

Funder Name
Polycystic Kidney Disease Charity

Alternative Name(s)
PKD Charity

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Royal College of Surgeons of England

Alternative Name(s)
RCS England, RCS ENG, The Royal College of Surgeons of England, RCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journals. The protocol is available on the study website https://roarstudy.co.uk/

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
Anonymised participant-level data will be available on reasonable request from Prof Diederik Bulters (d.bulters@soton.ac.uk). The data will be available after the publication of the study results for 10 years. Written requests for data from clinicians including a full study analysis plan will be reviewed on a case-by-case basis for scientific integrity. Data will be fully anonymised. Ethical permission was granted for sharing fully anonymised data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/03/2023	20/03/2023	Yes	No
HRA research summary			28/06/2023	No	No