

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

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<b>Registration date</b> 21/04/2021	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/09/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 hospital 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  
d.bulters@soton.ac.uk

## Contact information

### Type(s)

Public, Scientific

### Contact name

Mr Diederik Bulters

### ORCID ID

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**Type(s)**  
Scientific

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
276144

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

### **Study type(s)**

Other

### **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

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

**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, Medical Research Committee and Advisory 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

**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?
<a href="#">Protocol article</a>		16/03/2023	20/03/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes