

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

Submission date 07/04/2021	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/04/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/07/2024	Condition category 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 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?

Investigator initiated and funded

Who is the main contact?

Prof Diederik Bulter
d.bulter@soton.ac.uk

Study website

<https://www.roarstudy.co.uk>

Contact information

Type(s)

Public, Scientific

Contact name

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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]).

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

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
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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

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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

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+44 (0)2380 777222

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

Other

Funder Name

Investigator initiated and funded

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