

International Subarachnoid Aneurysm Trial

Submission date 23/10/2000	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 23/10/2000	Overall study status Completed	☐ Protocol
Last Edited 11/03/2015	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Andrew J Molyneux

Contact details

Oxford Neurovascular & Neuroradiology Research Unit (ONNRU)
West Wing, Level 6
John Radcliffe Hospital
Headley Way
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 234755
andy.molyneux@nds.ox.ac.uk

Additional identifiers

Protocol serial number

G9401611

Study information

Scientific Title

International Subarachnoid Aneurysm Trial

Acronym

ISAT

Study objectives

To compare the safety and efficacy of an endovascular treatment policy of ruptured intracranial aneurysms with a conventional neurosurgical treatment policy in an eligible population.

Primary objective: To determine whether an endovascular treatment policy of acutely ruptured intracranial aneurysms compared with a neurosurgical treatment policy, reduces the proportion of patients with a moderate or poor outcome (defined by Rankin grade 3-6) by 25% at one year.

Secondary objectives: To determine if:

1. This is as effective as neurosurgery in preventing re-bleeding from the treated aneurysm including long-term follow up
2. This results in a better quality of life than neurosurgery at one year (Euroqol measure)
3. This is more cost effective than neurosurgical treatment
4. This improves the neuropsychological outcome at one year (selected centres only)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Neuroscience, psychiatry

Interventions

1. Endovascular treatment policy of ruptured intracranial aneurysms
2. A conventional neurosurgical treatment policy

Intervention Type

Procedure/Surgery

Primary outcome(s)

Modified Ranking scale, Glasgow outcome scale, Neuropsychology assessment in some centres. Euroqol quality of life assessment, health economic evaluation including back to work rates

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/12/2007

Eligibility

Key inclusion criteria

1. Proven subarachnoid haemorrhage (SAH) on Computed Tomography (CT) or lumbar puncture
2. Presence of an intracranial aneurysm demonstrated by intra-arterial angiography likely to be responsible for the SAH
3. The patient in a clinical state that justifies treatment at some time by either surgical or endovascular means
4. Intracranial aneurysm judged to be suitable for either technique based on its angiographic anatomy and the responsible clinician is uncertain which is the best method of treatment
5. Appropriate consent of the patient or relatives

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. More than 28 days from SAH, unproven SAH
2. Unsuitable for both treatments
3. Refusal of consent
4. Patient participating in another trial

Date of first enrolment

01/01/1997

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Oxford Neurovascular & Neuroradiology Research Unit (ONNRU)
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation

Oxford Radcliffe Hospital NHS Trust (UK)

ROR

<https://ror.org/03h2bh287>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2005		Yes	No
Results article	results	01/08/2010		Yes	No
Results article	results	01/12/2011		Yes	No
Results article	results	21/02/2015		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes