ISRCTN49866681 https://doi.org/10.1186/ISRCTN49866681

International Subarachnoid Aneurysm Trial

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.surgery.ox.ac.uk/nvru/isat

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 (Euroquol 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1997

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

Age group
Adult

Sex
Both

Target number of participants
2143

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
England

United Kingdom

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

Sponsor information

Organisation
Oxford Radcliffe Hospital NHS Trust (UK)

Sponsor details
John Radcliffe Hospital
Headley Way
Oxford
England
United Kingdom
OX3 9DU

Sponsor type
Hospital/treatment centre

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

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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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