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Cerecyte coil trial

Submission date 09/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/10/2005	**Overall study status** Completed	
Last Edited 15/09/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.cerecytecoiltrial.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
05/Q1604/23

Study information

Scientific Title

Study objectives
To demonstrate that the rate of angiographic occlusion in the treatment of intracranial aneurysms is superior for patients treated with Cerecyte coils than for patients treated with standard bare platinum coils.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multicentre Research Ethics Committee (MREC), Oxfordshire REC A 18/052005; substantial amendment approved on 24/04/2006, ref: 05/Q1604/23

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Intracranial aneurysms

Interventions
1. Diagnostic 3D CTA or angiogram
2. Comparing a new approved endovascular coil device (Cerecyte) with existing platinum coil devices to produce occlusion of the aneurysm on follow-up angiography at 6 months
3. The patient will also have MRI angiography at 1 year

Amendments to interventions as of 30/05/2006:
1. Diagnostic three-dimensional computed tomographic angiography (3D CTA) or angiogram
2. Endovascular coil treatment
3. Follow-up angiography at 6 months (range 5-7 months) after treatment
4. MRI angiography between 12 and 24 months after treatment if deemed necessary and in line with normal practice at the recruiting centre

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Rate of angiographic occlusion of the aneurysm at 6 months to demonstrate if the rate of occlusion is superior for patients treated with Cerecyte coils compared with patients treated with bare platinum coils.

Amendments to primary outcome as of 30/05/2006:
Rate of angiographic occlusion of the aneurysm at 6 months to demonstrate whether the rate of occlusion is superior for patients treated with Cerecyte coils compared with patients treated with bare platinum coils.

Secondary outcome measures
1. Complication rate of treatment using Cerecyte coils compared to the standard bare platinum coils
2. Follow-up angiographic occlusion of the aneurysms treated with Cerecyte coils are more durable at 1 year

Amendments to secondary outcome as of 30/05/2006:
1. To observe the rate of procedural complications and adverse events for treatment using Cerecyte coils compared with standard bare platinum coils
2. To observe if retreatment rates are different between the two groups
3. To observe if a healing reaction is seen in a proportion of patients treated with Cerecyte coils and in no patients treated with standard platinum coils
4. Follow-up angiographic occlusion of the aneurysms treated with Cerecyte coils demonstrate that they are more durable at one year

Overall study start date
15/09/2005

Completion date
15/09/2007

Eligibility

Key inclusion criteria
1. Patients aged between 18 and 70 with a ruptured or unruptured intracranial aneurysm judged suitable for endovascular treatment by platinum coil occlusion
2. Aneurysm size of less than a 18 mm maximum lumen diameter and a neck width 2 mm or greater. 3D visualisation of neck on computed tomography angiography (CTA) or 3D angiography is desirable.
3. Patients planned for treatment of their aneurysm(s)
4. Patients capable of providing their own written informed consent (i.e. World Federation of Neurosurgical Societies [WFNS] grade 1 & 2) following subarachnoid haemorrhage (SAH) or undergoing treatment for an unruptured intracranial aneurysm (UIA)
5. Patient is willing and likely to return for follow-up angiography at 6 months (range 5-7 months) after treatment

6. Patient is willing to undergo a further imaging study at 12 months after treatment (magnetic resonance imaging [MRI] angiogram)

Amendments to inclusion criteria as of 30/05/2006
4. Patients capable of providing their own written informed consent (i.e.World Federation of Neurological Surgeons [WFNS] grade 1 and 2) following subarachnoid haemorrhage (SAH) or Rankin score 1 and 2 for those undergoing treatment for an unruptured intracranial aneurysm (UIA)
6. Patient is willing to undergo a further imaging study between 12 and 24 months after treatment (magnetic resonance imaging [MRI] angiogram or cerebral angiogram) if deemed necessary and possible, in line with normal practice at the recruiting centre

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Patients in poor grade after SAH (grade 3, 4 or 5)
2. Large aneurysms greater than 18 mm and giant aneurysms
3. Aneurysm neck narrower than 2 mm
4. Patient in whom stent placement is planned or performed (balloon assistance techniques allowed)
5. Patient is unwilling or unlikely to return for follow-up angiogram
6. Patients in whom that centre regard follow-up intra-arterial angiography not to be indicated
7. Lack of informed consent
8. The patient has undergone prior coil treatment or attempted treatment of the target aneurysm including prior surgical treatment

Date of first enrolment
15/09/2005

Date of final enrolment
15/09/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Neurovascular & Neuroradiology Research Unit (ONNRU)
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Sponsor information

Organisation
Micrus Endovascular Ltd. (UK)

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Sponsor type
Industry

Website
http://www.micrusendovascular.com

Funder(s)

Funder type
Industry

Funder Name
Micrus Endovascular Corporation (USA) (ref: RD/308/1)

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	clinical results	01/03/2012		Yes	No
Results article	angiographic results	01/10/2012		Yes	No
Results article	results	01/01/2014		Yes	No