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# Cerecyte coil trial

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
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.

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### 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
United Kingdom

England

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

**Organisation**
Micrus Endovascular Ltd. (UK)

# Funder(s)

**Funder type**
Industry

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

# 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 | clinical results | 01/03/2012 | | Yes | No |
| Results article | angiographic results | 01/10/2012 | | Yes | No |
| Results article | results | 01/01/2014 | | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |