

On-line Table 1: Baseline characteristics of enrolled patients

| | Ruptured | | Unruptured | | All | |
|---------------------------|------------------------------------|--|------------------------------------|--|------------------------------------|--|
| | Cerecyte (n = 114) (No.) (%) | Bare Platinum (n = 119) (No.) (%) | Cerecyte (n = 133) (No.) (%) | Bare Platinum (n = 131) (No.) (%) | Cerecyte (n = 247) (No.) (%) | Bare Platinum (n = 250) (No.) (%) |
| Female | 68 (59.6) | 77 (64.7) | 105 (78.9) | 104 (79.4) | 173 (70.0) | 181 (72.4) |
| Age (yr) (mean) (SD) | 48.5 (10.2) | 50.3 (10.4) | 51.7 (10.2) | 51.8 (9.8) | 50.2 (10.3) | 51.1 (10.1) |
| Target aneurysm size (mm) | | | | | | |
| 2–4.9 | 17 (14.9) | 21 (17.6) | 22 (16.5) | 21 (16.0) | 39 (15.8) | 42 (16.8) |
| 5–9.9 | 80 (70.2) | 85 (71.4) | 97 (72.9) | 96 (73.3) | 177 (71.7) | 181 (72.4) |
| 10–18 | 17 (14.9) | 13 (10.9) | 14 (10.5) | 14 (10.7) | 31 (12.6) | 27 (10.8) |
| Dome-to-neck ratio (mm) | | | | | | |
| ≤1.5 | 15 (13.2) | 13 (10.9) | 32 (24.1) | 33 (25.2) | 47 (19.0) | 46 (18.4) |
| >1.5 | 99 (86.8) | 106 (89.1) | 101 (75.8) | 98 (74.8) | 200 (81.0) | 204 (81.6) |
| Aneurysm location | | | | | | |
| Internal carotid | 37 (32.4) | 42 (35.3) | 65 (48.9) | 73 (55.7) | 102 (41.3) | 115 (46.0) |
| Anterior cerebral | 50 (43.8) | 43 (36.1) | 19 (14.3) | 23 (17.5) | 69 (27.9) | 66 (26.4) |
| Middle cerebral | 16 (14.0) | 20 (16.8) | 27 (20.3) | 21 (16.0) | 43 (17.4) | 41 (16.4) |
| Posterior circulation | 11 (9.6) | 14 (11.8) | 22 (16.5) | 14 (10.7) | 33 (13.4) | 28 (11.2) |

On-line Table 2: Adverse procedural events up to 24 hours^a

| | Ruptured | | P | Unruptured | | P | All | | P |
|---|------------------------------------|--|------|------------------------------------|--|-----|------------------------------------|--|------|
| | Cerecyte (n = 114) (No.) (%) | Bare Platinum (n = 119) (No.) (%) | | Cerecyte (n = 133) (No.) (%) | Bare Platinum (n = 131) (No.) (%) | | Cerecyte (n = 247) (No.) (%) | Bare Platinum (n = 250) (No.) (%) | |
| No. of patients with adverse procedural events | 21 (18.4) | 13 (10.9) | .052 | 15 (11.3) ^b | 12 (9.2) | .28 | 36 (14.6) | 25 (10.0) | .060 |
| Aneurysm rupture | 8 (7.0) | 5 (4.2) | .18 | 3 (2.3) | 2 (1.5) | .33 | 11 (4.5) | 7 (2.8) | .16 |
| Thromboembolic complication | 7 (6.1) | 4 (3.4) | .16 | 10 (7.5) ^c | 7 (5.3) | .24 | 17 (6.9) | 11 (4.4) | .11 |
| Other complications grouped | 6 (5.3) ^e | 4 (3.4) ^f | .24 | 3 (2.3) ^g | 3 (2.3) ^h | .51 | 9 (3.6) | 7 (2.8) | .30 |
| Failed embolizations (no coils placed) ^d | 1 (0.9) | 4 (3.4) | .91 | 6 (4.5) | 3 (2.3) | .16 | 7 (2.8) | 7 (2.8) | .49 |

^a P values are for 1-sided Blackwelder tests.

^b One patient had both a procedural aneurysm rupture and a thromboembolic complication.

^c Two patients who had a thromboembolic event within 24 hours were included as defined in the trial protocol.

^d Reasons for failure: 5 unsuitable anatomies, 4 catheter problems, 2 inability to place coils, 3 not known. Of these, 1 patient was successfully coiled 1 week later, 4 had clipping, 9 remained untreated (7 UIA, 2 ruptured; of these, 1 had a follow-up MRI at 2/12 but no further treatment, and 1 had no follow-up).

^e Three coil-related: 1 tail protrusion of last coil, 1 first coil placed then difficulty recatheterizing aneurysm, 1 failure to place Cerecyte coils so platinum coils used (crossover); 3 complications unrelated to coils.

^f One coil-related: small coil tail in parent vessel; 3 complications unrelated to coils.

^g Three complications unrelated to coils.

^h Two coil-related: 1 loop of first coil in parent artery, 1 coil loop in middle cerebral artery inferior trunk.

On-line Table 3: Adverse periprocedural events up to 24 hours resulting in neurological deterioration^a

| | Ruptured | | P | Unruptured | | P | All | | P |
|--|------------------------------------|--|-----|------------------------------------|--|------|------------------------------------|--|------|
| | Cerecyte (n = 114) (No.) (%) | Bare Platinum (n = 119) (No.) (%) | | Cerecyte (n = 133) (No.) (%) | Bare Platinum (n = 131) (No.) (%) | | Cerecyte (n = 247) (No.) (%) | Bare Platinum (n = 250) (No.) (%) | |
| No. of patients with neuro-deterioration | 5 (4.4) | 3 (2.5) | .22 | 5 (3.8) | 2 (1.5) | .13 | 10 (4.0) | 5 (2.0) | .091 |
| Neuro-deterioration: aneurysm rupture | 2 (1.8) | 1 (0.8) | .27 | 2 (1.5) | 0 (0.0) | .077 | 4 (1.6) | 1 (0.4) | .087 |
| Neuro-deterioration: thromboembolic | 1 (0.9) | 1 (0.8) | .49 | 2 (1.5) | 1 (0.8) | .28 | 3 (1.2) | 2 (0.8) | .32 |
| Neuro-deterioration: other causes | 2 (1.8) | 1 (0.8) | .27 | 1 (0.8) | 1 (0.8) | .50 | 3 (1.2) | 2 (0.8) | .32 |

^a P values are for 1-sided Blackwelder tests.

On-line Table 4: Postprocedural adverse events, >24 hours to discharge^a

| | Ruptured | | | Unruptured | | | All | | |
|---|--|--|----------|--|--|----------|--|--|----------|
| | Bare | | <i>P</i> | Bare | | <i>P</i> | Bare | | <i>P</i> |
| | Cerecyte (<i>n</i> = 114) (No.) (%) | Platinum (<i>n</i> = 119) (No.) (%) | | Cerecyte (<i>n</i> = 133) (No.) (%) | Platinum (<i>n</i> = 131) (No.) (%) | | Cerecyte (<i>n</i> = 247) (No.) (%) | Platinum (<i>n</i> = 250) (No.) (%) | |
| Delayed cerebral ischemic deficit (vasospasm) | 14 (12.3) | 15 (12.6) | .53 | 1 (0.8) ^b | 0 (0.0) | .16 | 15 (6.1) | 15 (6.0) | .49 |
| Neuro-deterioration | 10 (8.8) ^c | 15 (12.6) ^d | .83 | 2 (1.5) ^e | 3 (2.3) ^f | .68 | 12 (4.9) | 18 (7.2) | .86 |
| Infection | 6 (5.3) | 6 (5.0) | .47 | 3 (2.3) | 3 (2.3) | .51 | 9 (3.6) | 9 (3.6) | .49 |
| Hydrocephalus | 4 (3.5) | 5 (4.2) | .61 | 1 (0.8) ^b | 1 (0.8) ^b | .50 | 5 (2.0) | 6 (2.4) | .61 |
| Pulmonary complications | 3 (2.6) | 2 (1.7) | .31 | 2 (1.5) | 0 (0.0) | .077 | 5 (2.0) | 2 (0.8) | .12 |
| Seizures | 0 (0.0) | 0 (0.0) | – | 0 (0.0) | 1 (0.8) | .84 | 0 (0.0) | 1 (0.4) | .84 |
| Death ^g | 2 (1.8) | 0 (0.0) | .077 | 0 (0.0) | 0 (0.0) | – | 2 (0.8) | 0 (0.0) | .078 |
| Other ^h | 10 (8.8) | 16 (13.4) | .87 | 10 (7.5) | 8 (6.1) | .32 | 20 (8.1) | 24 (9.6) | .72 |

^a *P* values are for 1-sided Blackwelder tests.

^b Vasospasm and hydrocephalus in the unruptured group were associated with procedural rupture and SAH.

^c Seven vasospasm (1 died), 2 hydrocephalus, 1 postprocedural rebleed (died).

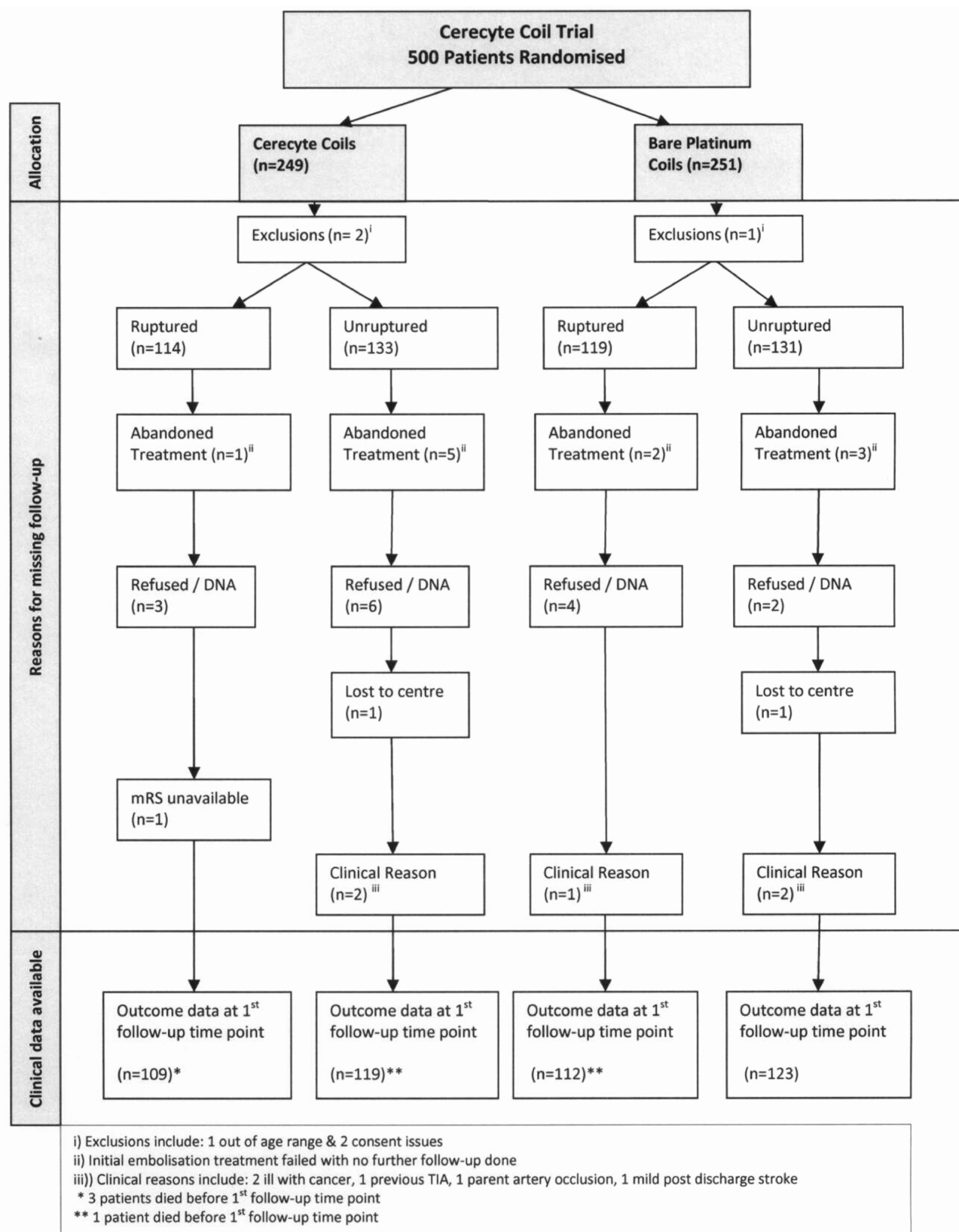
^d Seven vasospasm, 2 thrombolytic, 2 hydrocephalus, 1 TIA, 2 complications of SAH, 1 hemiparesis postclipping.

^e One vasospasm, 1 hydrocephalus.

^f One hydrocephalus, 1 thromboembolic, 1 complication due to medication.

^g Causes of death: delayed cerebral ischemia due to vasospasm, postprocedural rebleed.

^h Other includes 9 cardiac, 15 groin complications (5 classed as serious groin hematoma), 4 pain (nonheadache), and 16 general complications of SAH.



On-line Fig 1. Consort diagram showing patient flow to secondary end point—clinical outcome; DNA indicates did not attend.