

Animation Script

Cavernomas: A Randomised Effectiveness (CARE) Pilot Study

What was the question?

A cavernoma is a cluster of blood vessels that can cause symptoms by bleeding to cause a stroke, or by triggering epileptic seizures. Medical care of people with cavernoma involves things like anti-seizure drugs and physiotherapy. Treatment with surgery can also be done: with neurosurgery to remove the cavernoma, or with stereotactic radiosurgery to stabilise the cavernoma. The pros and cons of using surgery to treat these types of cavernoma are finely balanced.

Why was this question asked?

In 2015, patients, doctors and researchers were asked for their top unanswered questions about cavernoma. People wanted to know whether surgery in addition to medical care reduced bleeds or seizures for patients. Research funders wanted to know if it would be possible to run a trial to give answers, so they funded a pilot study.

What did we do?

Doctors, researchers and representatives of Cavernoma Alliance UK and Cavernoma Ireland worked on this pilot study from August 2021 to January 2024. We set up a network of specialists at hospitals in the UK and Ireland, aiming to recruit 60 people with a symptomatic brain cavernoma <on screen only - explanation of randomised controlled trial, comparing medical care alone v treatment with surgery and medical care>. We also studied why some people took part and others did not.

What did we find?

28 hospitals took part of 40 that were invited. Specialists assessed 322 eligible patients. 68 adults and 4 children took part in the pilot, and 67 people were assessed 6 months later. There were two key barriers to people joining the study. Firstly, doctors currently recommend medical care in most cases, and not all doctors felt comfortable offering surgery more widely. In addition, people mostly preferred medical care over any surgery, and stereotactic radiosurgery over neurosurgery, so preferred to choose this than take part. Recruitment was better for specialists who presented the trial to patients as a solution to the uncertainty of the finely balanced pros and cons of surgery. The number of patients who had strokes during follow-up was the same for people with surgery plus medical care, as it was for those with medical care alone. There were no deaths or serious adverse events.

What does this mean?

We showed that a randomised trial of surgery for brain cavernoma is possible. We recruited more people than planned and found what helped or stopped recruitment. While the results of this pilot study aren't conclusive, our learning can be used to inform the design of a bigger international trial.

We thank everyone who was involved. You can find out more:

- Cavernoma Alliance UK website: <https://cavernoma.org.uk/care-study>
- Study website: www.ed.ac.uk/care-study
- Published results:
[https://www.thelancet.com/journals/laneur/article/PIIS1474-4422\(24\)00096-6/fulltext](https://www.thelancet.com/journals/laneur/article/PIIS1474-4422(24)00096-6/fulltext)
[https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(24\)00136-6/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(24)00136-6/fulltext)