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Synopsis

Medical management and intervention (using neurosurgical resection or stereotactic radiosurgery) versus medical management alone for symptomatic brain cavernoma: the CARE pilot RCT

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Published August 2025
DOI: 10.3310/GJRS5321
Volume 29 • Issue 38

Plain language summary

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Health Technology Assessment 2025; Vol. 29: No. 38
DOI: 10.3310/GJRS5321

NIHR Journals Library www.journalslibrary.nihr.ac.uk

This synopsis should be referenced as follows:
Al-Shahi Salman R, Kitchen N, Forsyth L, Ganesan V, Hall PS, Harkness K, *et al*. Medical management and intervention (using neurosurgical resection or stereotactic radiosurgery) versus medical management alone for symptomatic brain cavernoma: the CARE pilot RCT. *Health Technol Assess* 2025;**29**(38). https://doi.org/10.3310/GJRS5321

Plain language summary

What was the question?

A cavernoma is a cluster of blood vessels in the brain, which can bleed and cause a stroke, or cause a seizure or epilepsy. Intervention involves surgery to remove the cavernoma or stereotactic radiosurgery to stabilise the cavernoma with focused radiation. The pros and cons of cavernoma treatment with or without intervention are finely balanced. In this pilot study, we aimed to find out whether a separate, definitive randomised trial could be done to compare treatment of symptomatic cavernomas with or without intervention.

What did we do?

Doctors, researchers and representatives of the United Kingdom and Ireland advocacy organisations for people with cavernoma worked on this project from August 2021 to January 2024. We set up a network of specialists at hospitals in the United Kingdom and Ireland. These specialists aimed to recruit 60 people with a brain cavernoma that had caused symptoms to join a randomised controlled trial comparing treatment of their brain cavernoma with or without intervention. We studied why some people took part and others did not.

What did we find?

Twenty-eight hospitals in the United Kingdom took part of 40 that we invited. Specialists assessed 322 eligible patients, 72 took part in the trial after a recruitment extension and 67 were assessed 6 months later. The biggest barrier to taking part was that usual care tended to avoid intervention. Recruitment was better for specialists who offered intervention to more people than in usual care and presented the trial as a solution to uncertainty. Two of 33 patients who had treatment with intervention had a stroke, and two of 34 patients who had treatment without intervention had a stroke, but there were no other serious adverse events or deaths.

What does this mean?

We recruited more people than planned and found what helped or stopped recruitment. The results can inform the design of a definitive trial, which would need to be done internationally due to rarity of eligible people.