A randomised, double blind, placebo-controlled trial of a two-week course of dexamethasone for adult patients with a symptomatic Chronic Subdural Haematoma (Dex-CSDH trial)

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Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/XWZN4832.

Primary conflicts of interest: Peter J Hutchinson was a member of the Health Technology Assessment (HTA) Programme Intellectual Property Panel (January 2016 to May 2018), and is currently a member of the HTA Prioritisation Committee B (in hospital). Antonio Belli reports being employed by and owning shares in Marker Diagnostics (Birmingham, UK). Elizabeth A Warburton is currently a member of the HTA Clinical Evaluation and Trials Committee (2019–present). Garry Barton was a member of the Norwich Clinical Trials Unit funded by the National Institute for Health and Care Research (NIHR) (until August 2021). Ian Wilkinson was a member of the Cambridge Clinical Trials Unit funded by NIHR (until August 2021). Simon Bond was a member of the Efficacy and Mechanism Evaluation Funding Committee (May 2015 to May 2019). Ellie Edlmann reports grants from Royal College of Surgeons and Rosetrees Trust Research Fellowship, during the conduct of the study. Carol Davis-Wilkie was funded as an employee of the Cambridge Clinical Trials Unit.

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Plain language summary

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Plain language summary

Chronic subdural haematoma is one of the most common conditions managed in adult neurosurgery and mainly affects older people. It is an 'old' collection of blood and blood breakdown products found on the surface of the brain. Surgery to drain the liquid collection is effective, with most patients improving. Given that inflammation is involved in the disease process, a commonly used steroid, dexamethasone, has been used alongside surgery or instead of surgery since the 1970s. However, there is no consensus or high-quality studies confirming the effectiveness of dexamethasone for the treatment of chronic subdural haematoma.

This study was designed to determine the effectiveness of adding dexamethasone to the normal treatment for patients with a symptomatic chronic subdural haematoma. The benefit of adding dexamethasone was measured using a disability score called the Modified Rankin Scale, which can be divided into favourable and unfavourable outcomes. This was assessed at 6 months after entry into the study.

In total, 748 adults with a symptomatic chronic subdural haematoma treated in neurosurgical units in the UK participated. Each participant had an equal chance of receiving either dexamethasone or a placebo because they were assigned randomly. Neither the patients nor the investigators knew who received dexamethasone and who received placebo.

Most patients in both groups had an operation to drain the haematoma and experienced significant functional improvement at 6 months compared with their initial admission to hospital. However, patients who received dexamethasone had a lower chance than patients who received placebo of favourable recovery at 6 months. Specifically, 84% of patients who received dexamethasone had recovered well at 6 months, compared with 90% of patients who received placebo. There were more complications in the group that received dexamethasone.

This trial demonstrates that adding dexamethasone to standard treatment reduced the chance of a favourable outcome compared with standard treatment alone. Therefore, this study does not support the use of dexamethasone in treating patients with a symptomatic chronic subdural haematoma.

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