Plasma exchange and glucocorticoids to delay death or end-stage renal disease in anti-neutrophil cytoplasm antibody-associated vasculitis: PEXIVAS non-inferiority factorial RCT

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Plain English summary

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Plain English summary

A nti-neutrophil cytoplasm antibody vasculitis is a rare and severe disease in which the patient makes antibodies that damage their blood vessels. It can cause lung damage, kidney failure and early death. Treatment aims to suppress the harmful effects of the antibodies and associated inflammation. In particular:

- 1. Plasma exchange aims to remove the antibodies from the bloodstream.
- 2. Steroids aim to reduce the harmful activity of the antibodies.

Unfortunately, plasma exchange is expensive and time-consuming, and we do not know if it really works long term to reduce kidney damage or the risk of death. We know steroids work, but they have many severe side effects that are related to higher doses. Again, we do not know if lower doses are equally effective.

We conducted a randomised trial, PEXIVAS (Plasma Exchange In VASculitis), to measure the clinical effectiveness of plasma exchange and of reduced steroid doses. Anti-neutrophil cytoplasm antibody vasculitis patients with severe kidney or lung disease were allocated randomly to either plasma exchange or no plasma exchange. The same patients were then randomly allocated to a 'reduced' or 'standard' steroid dose. All patients received an immunosuppressive drug: cyclophosphamide or rituximab. The primary end point for both trials was the occurrence of either kidney failure or death.

A total of 704 patients were recruited between 2010 and 2016, and they were followed up until the end of the trial in July 2017. Ninety-nine patients died and 138 developed kidney failure. Plasma exchange did not reduce the chances of death or kidney failure. There was also no difference between the two steroid dose groups in the number of deaths or patients developing kidney failure. However, there were fewer serious infections in the reduced steroid dose group.

These results do not support the routine use of plasma exchange for all patients with severe vasculitis. They do show that the reduced-dose steroid regimen is just as effective as, and safer than, a 'standard'-dose steroid regimen. These results have the potential to save money and make the treatment of vasculitis patients safer in the future.

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This report

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