



Synopsis

Control, Fludrocortisone or Midodrine for the treatment of Orthostatic Hypotension: CONFORM-OH pilot RCT and economic evaluation

Helen Mossop,¹ Sarah Al Ashmori,¹ Tumi Sotire,² Emma Clark,³
Gillian Watson,³ Miles Witham,^{4,5} Luke Vale,² Naomi McGregor,³
Julia Phillipson,³ James MS Wason,¹ Alison J Yarnall,^{6,7}
Helen Hancock,³ Rose Anne Kenny⁸ and James Frith^{1,7*}

¹Population Health Sciences Institute, Newcastle University, Newcastle upon Tyne, UK

²Health Economics Group, Population Health Sciences Institute, Newcastle University, Newcastle upon Tyne, UK

³Newcastle Clinical Trials Unit, Newcastle University, Newcastle upon Tyne, UK

⁴AGE Research Group, Translational and Clinical Research Institute, Faculty of Medical Sciences, Newcastle University, Newcastle upon Tyne, UK

⁵NIHR Newcastle Biomedical Research Centre, Newcastle upon Tyne Hospitals NHS Foundation Trust, Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust and Newcastle University, Newcastle upon Tyne, UK

⁶Translational and Clinical Research Institute, Newcastle University and Newcastle upon Tyne NHS Foundation Trust, Newcastle upon Tyne, UK

⁷The Newcastle upon Tyne Hospitals NHS Trust, Newcastle upon Tyne, UK

⁸Medical Gerontology, School of Medicine, Trinity College Dublin, Dublin, Ireland

*Corresponding author james.frith@newcastle.ac.uk

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Plain language summary

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Plain language summary

Orthostatic hypotension is a large drop in blood pressure which occurs on standing upright. It is very common but the best way to treat it is not known. This clinical trial aimed to find out whether three common treatments help to improve the condition and are value for money. The treatments were non-drug therapies (such as water and salt and compression garments) and two medications – fludrocortisone and midodrine.

The trial included a 10-month pilot (rehearsal) to see whether a full trial would be feasible. The pilot evaluated how many participants it was possible to recruit, how many dropped out and whether participants changed their allocated treatment. The outcomes (which measure if a treatment is effective) were evaluated to see how well they were completed. Feedback was gained from the NHS hospital sites that were involved and the participants who volunteered.

The study began in November 2019. The UK went into lockdown for the COVID-19 pandemic in March 2020. This resulted in delays to the start of the trial and a shortage of staff available to work on the study. At the end of the pilot, 282 adults with OH had been identified at nine sites across the UK. Of these, 233 did not meet the criteria to take part. For just over half (52%), this was because they were already taking one of the study treatments. In 9 months, only 13 participants had been recruited (the target was at least 40). Of these, 3 dropped out so results were available in 10 participants at 6 months.

The number of participants is too small to measure how effective the treatments are. To answer the research question a clinical trial would need to be designed differently, focusing on ways to recruit more participants and support clinical staff to deliver the study.