



CONFORM-OH

Control, Fludrocortisone or Midodrine for the treatment of Orthostatic Hypotension: A Randomised Controlled Trial

Newsletter 2.0

May 2022



Welcome!

Welcome to the second Newsletter for the CONFORM-OH Trial.

The Chief Investigator, James, and the Newcastle Clinical Trials Unit (NCTU) Team are delighted that you are part of the trial.

Recruitment and site opening update

Since the last Newsletter, we have opened further trial sites, in Lewisham, Gateshead, Bath and Exeter, and recruited four participants in each of Walsall and Newcastle. **Congratulations and thanks to staff at The Newcastle upon Tyne Hospitals NHS Foundation Trust, and Walsall Healthcare NHS Trust!** **This is a total of nine participants in the trial, to date.** Sites in Glasgow and Salford have had Site Initiation Meetings, and others have had initial site meetings with the CI. Several patients have been pre-screened for trial eligibility, so we hope to have more participants very soon!

Monthly trial site meeting

We plan to hold a monthly trial site meeting, to which all site staff members involved in the trial are invited. This is an opportunity to meet other staff involved in the trial, share ideas, and have your questions answered by the NCTU team.



Don't forget to use the handy trial appointment task lists for each trial visit – find them in Section 13.5 of your ISF

AIM: To evaluate clinical and cost effectiveness of three treatment strategies for OH

CHIEF INVESTIGATOR

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Completed Eligibility Checklists and Consent Forms

Please remember to email your completed Eligibility Checklists and Consent Forms **securely**, to: nctu.conform-oh.conf@nhs.net

This ensures that no patient identifiable data (PID) are transferred from site to NCTU. Failure to do this will result in a Deviation, and repeated failure a Violation, which we must avoid.

Definitions for CPMS/SReDA entries

We are grateful for your assistance in entering your recruitment data to the CPMS system (SReDA in Scotland), and these figures come through to the NCTU for checking, on a monthly basis. In order to ensure that we are all familiar with the terminology, we have put together some definitions to help you to enter the data correctly:

Consented The participant provided informed consent to join a study.

Recruited The participant provided informed consent to join a study and is taking part in the study (having been deemed eligible according to any screening tests applicable).

Failed Screening – not applicable to CONFORM-OH – do not use! The participant has given consent to non standard clinical investigations, procedures or tests relating to the study, but following these procedures was found to be ineligible to take part in the study.

Timelines – Please upload your data on, or just after, the first of the month, up to and including the previous month's data. This gives the NCTU team time to confirm the data for all sites, on the CPMS system, by the end of each month.

Contraindications and Previous Use of Study Drugs

The next database update will include asking some additional questions on the screening log about which of the study drugs the participant has previously taken or had a contraindication to. Until the update is processed we may ask this via a query in the database. If you are able to provide this information it would be very helpful to help us monitor any barriers to recruitment.

FREQUENTLY ASKED QUESTIONS

When is the Consent Form complete? The Consent Form is complete when there are two sets of information, and two signatures on one paper document. This is for the person giving consent, and the person obtaining consent. We realise that this could include two different dates, if the consent process was carried out remotely, eg over the phone, but this is acceptable, and will be checked at monitoring.

Can we schedule assessments on the same day? Yes, as long as the patient has had 24 hours to consider participation in the trial. Don't forget that you can use at home and/or phone visits, to carry out trial tasks – don't forget about blood pressure (BP) measurements, and carry out a pregnancy test if necessary.

[Trial website](#)

Please continue to refer to the trial website, for information including news and useful links <http://research.ncl.ac.uk/conform-oh/>

We appreciate that you have many conflicting demands on your time, just now, and thank you for keeping CONFORM-OH at the forefront of your thoughts, as you care for your patients.