CONFORM-OH

Control, **F**ludrocortisone **or** **M**idodrine for the treatment of **O**rthostatic **H**ypotension: A Randomised Controlled Trial

Newsletter 1.0 Feb 2022

Newcastle University

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

CHIEF INVESTIGATOR

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Welcome!

Welcome to the first 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

Our first site, Newcastle, opened to recruitment on 2 December 2021 and we have three additional sites in Walsall, Dumfries and Norwich. **The first participant was recruited by the Dumfries site on 23 February 2022! Congratulations and thanks to all at NHS Dumfries & Galloway.** Sites in Gateshead, Exeter and Lewisham have had Site Initiation Meetings, and more are scheduled. Several patients have been pre-screened for trial eligibility, so we hope to have more participants very soon!

Trial website

Our Trial website launched on 25 February 2022, and here you can find trial information including news and PPI details, links to trial documents like the protocol and Patient Information Leaflet, for your reference, the training videos that you watched during site initiation, and staff contacts – trial management, collaborators, and PI and a trial contact at each site.

http://research.ncl.ac.uk/conform-oh/

Screening Log Reminder

As per protocol we will collect screening data within the screening log eCRF in the database. Please ensure you update this regularly to capture all screened patients and the reasons for ineligibility or decline, if applicable. There is a paper log available in your Investigator Site File (ISF) to support you to collect this data. Please also remember not to start screening activity until you have Green Light Approval.

TRIAL AMENDMENTS

Substantial Amendment 01, and Non-substantial Amendments 01 and 02 were approved recently, to remove the requirement for out-of-hours cover for the trial, add in new trial sites, include roles other than Research Nurse in the poster and correct various errors in trial documents. You should now be working to the following *new* documents, which were circulated in January 2022:

Document	Version Number	Date
CONFORM-OH Protocol	4.0	04/01/2022
CONFORM-OH Patient Information Leaflet (footer corrected)	3.0	30/09/2021
CONFORM-OH Patient Study Card	2.0	30/09/2021
CONFORM-OH Consent Form (footer corrected)	2.0	30/09/2021
CONFORM-OH Participant Withdrawal form	2.0	30/09/2021
CONFORM-OH Falls Diary *	3.0	30/09/2021
CONFORM-OH HSU Questionnaire - Baseline 3 6 Months	2.0	21/07/2021
CONFORM-OH Time and Travel Questionnaire	2.0	30/09/2021
CONFORM-OH Home Blood Pressure instructions	2.0	02/11/2021
CONFORM-OH Omron BP machine Instruction Leaflet 1 ∞	N/A	N/A
CONFORM-OH Omron BP machine Instruction Leaflet 2 ∞	N/A	N/A
CONFORM-OH Publicity poster	2.0	20/01/2022

* Please note that printed Falls Diary booklets will be sent to you in the post
∞ These leaflets are included with the BP Monitor sent to you in the post

If you do not have these documents in your ISF please let us know, and we will send them to you.

FREQUENTLY ASKED QUESTIONS

Can more than one member of site staff complete the screening log? Yes – if it is easier to have individual investigators completing the screening log (so you would have multiple logs), each investigator should have a unique number built in to the screening number for each participant eg XX1001 indicates site number XX, recruiter number 1 (digit three: 1), and participant 001. A second investigator would be XX2001, and so forth

Is there any Pharmacy involvement in the trial? No – there is no Pharmacy monitoring, or monitoring of compliance (you don't need to count returned medication or return anything to Pharmacy); we fit in with your normal prescribing and dispensing procedures

Can we recruit from both clinics and the wards? Yes – tell the people you work with about the trial! Don't forget about the trial poster, which you can use to publicise our research, and please do provide your colleagues with the PIL to give to potentially eligible patients

Can we randomize participants who are on 'culprit medications'? It depends. As long as you would be happy for them to be randomised to any one of the intervention arms. Follow your usual clinical practice, which might mean stopping the culprit medications and reviewing before randomization.

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.