No progress Excellent progress

SIGNED A Marshall DATE 20.05.24.....

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Report Summary

Primary aim:

The primary aim of the study was to determine the repeatability and reproducibility of Hoffmann reflex rate dependent depression (HRDD), a biomarker of spinal disinhibition in a clinical population – patients with painful diabetic neuropathy (pDPN).

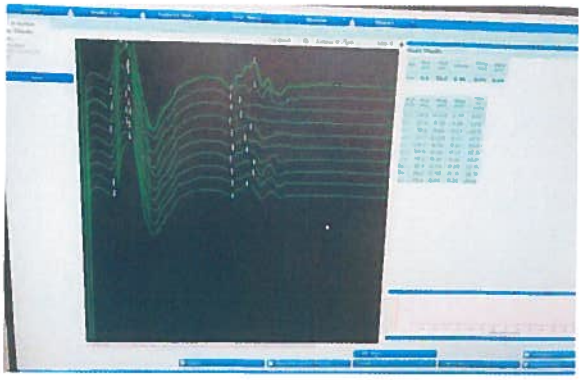
Progress:

Due to delays obtaining ethical approval, recruitment to the study began later than anticipated. However, now that the necessary approvals are in place, recruitment has commenced and is progressing at a steady pace.

4 participants have completed the repeatability and reproducibility visits.
1 participant has completed the baseline visit and are scheduled to return for there repeat assessments.

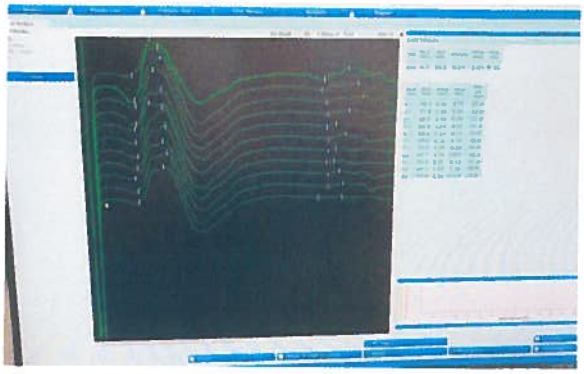
Example of repeatability and reproducibility traces

HRDD (H1/meanH2-5) @ 1Hz = 33.9



HRDD (H1/meanH2-5) @ 1Hz = 30.7

HRDD (H1/meanH2-5) @ 3Hz = 32.4



HRDD (H1/meanH2-5) @ 3Hz = 48.6

Comments on data collected so far:

Quality control of data acquisition appears to be crucial for this study. Whilst only a small amount of data has been collected so far, participants with technically good HRDD recordings appear to show good repeatability and reproducibility. The largest discrepancies in reproducibility appear to be when technically sub-optimal recordings have been obtained (see above recordings at 3Hz which show variable M-wave amplitudes). Technical excellence must be a focus for the remaining data collection.

Secondary aim:

The study also aimed to generate indicative data as to whether HRDD or a change in HRDD predicted the therapeutic response to duloxetine, therefore making HRDD a reliable and valid biomarker for detecting spinal disinhibition for use in clinical trials and predicting treatment responses in the clinic.

Progress:

Due to the delayed start of study recruitment, we have not reached week 9 assessments for any of the participants with painful diabetic neuropathy. The first participant will return for this assessment at the beginning of June.

Following the initial delays and the requirement to obtain an extension to the study recruitment period, I am confident that we will meet target recruitment within the remaining study time frame.