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Study Title: A Randomised, Cross-over Study to Compare the Efficacy of Lidocaine 5% Plasters versus Pregabalin in the Treatment of Complex Regional Pain Syndrome, Type 1.
Chief Investigator: Dr R Krishnamoorthy
EudraCT Number: 2009-010557-12
UK Sponsor Details: The Pennine Acute Hospitals NHS Trust (PAHT)
REC ref: 11/NW/0758

This study was approved by NRES Committee North West – Liverpool Central on 01/03/2012. Unfortunately the study failed to proceed any further. Records show that the study was registered with PAHT from 2009 but despite receiving external support from phlexglobal this study took a significant time to set up. Phlexglobal also formally raised their concerns about the length of time this trial took to set-up.

The R&D committee at PAHT reviewed the governance arrangements attached to sponsoring a CTIMP. To be compliant with UK law, sponsorship of a CTIMP would have resulted in a disproportionate volume of work for the PAHT R&D office. The risk attached to sponsoring a CTIMP is significant. At the time the above trial was the only CTIMP which PAHT had agreed to sponsor. Most of the R&D team were funded via the CLRN and the trial was not listed on the NIHR portfolio, which meant that any involvement from the R&D office would breach PAHT's contract with the CLRN.

In view of the above, PAHT R&D committee discussed sponsorship of CTIMPs at length and concluded that the R&D office did not have the infrastructure to sponsor trials of this nature. The CI was notified that PAHT was unable to act as sponsor for this trial and was advised to contact the R&D office of his new employer with a view to them acting as Trial sponsor.

Although Wrightington Wigan & Leigh NHS Foundation Trust (WWL) agreed to take on the role of sponsor they have since confirmed that sponsorship was not formally transferred and the study did not reach approval and therefore did not commence.

The CI has also confirmed that the study did not start but does not remember the date it was abandoned. Therefore, PAHT will consider abandonment as the date when the CI was informed that PAHT were unable to act as sponsor, 24/09/2012.

Contributors to the report (via email):

- Dr R Krishnamoorthy, Chief Investigator
- Sandra Latham, R&D Coordinator, Wrightington, Wigan, and Leigh NHS Foundation Trust
- Beverley Greenhalgh, Sponsorship Support & Compliance Manager, Northern Care Alliance NHS Group

Report details compiled and prepared on behalf of Sponsor by Beverley Greenhalgh, Sponsorship Support & Compliance Manager, 21st November 2019