

The Clinical Research Nurse as an expert resource in the protocol development and implementation of a research study – a case report

Polly Tarrant, Lead Research Nurse, Kornelia Hathaway, Education and Training Manager
Wellcome Trust Clinical Research Facility (WTCRF), Cambridge

The function of the WTCRF is to support and encourage high calibre research and ensure that it is carried out safely and to the highest possible standards as well as to provide assistance throughout the research process from trial design to data collection and study management.

Clinical Research Nurse (CRN)

The role is reflected in the core competencies identified by the Clinical Research Nurse Competency Framework (RCN 2008)

- To demonstrate knowledge and understanding of the evolution of clinical research.
- To apply knowledge and skills in the clinical research environment.
- To work within and adhere to the requirements of research ethics, research governance and legislation.
- To understand the principles and practice of obtaining and maintaining valid informed consent.

Following ethics and R&D approvals, there were still a number of issues to be resolved prior to running the study. The on-going contribution of the CRN to resolve these - in collaborating with the study team on these issues - reflects the level of specialist expertise intrinsic to the role.

Drug administration issues that needed clarification

Rate of IV administration
Dilution/ concentration/ drug compatibility
Procedure for administration
Equipment training

The Clinical Research Nurse's role and contribution:

- Setting up pilot study visit
- There was no IV monograph or IV medicine information sheet for methamphetamine, so liaised with Trust Pharmacy to establish monograph (eg, by providing evidence of precedents of practice of similar studies)
- Established, reviewed and amended the drug administration procedure - informed by clinical experience of IV drug administration and awareness of Trust and regulatory requirements in relation to equipment competence

Participant safety issues

Managing side effects of all study drugs
Rigorous monitoring of participant vital signs required as methamphetamine has known cardiovascular effects.
Drug screening originally excluded participants only if methamphetamine use detected and not use of other recreational drugs

- Patient advocacy integral part of CRN's role
- Clarified and documented expected side effects of study drugs.
- Initiated and arranged provision of rescue drugs – including procyclidine hydrochloride in case of muscle rigidity due to amisulpride
- As pilot study identified insomnia following methamphetamine administration, established process for participants to receive discharge medication of zopiclone x 2 doses (to be taken as required)
- Robust monitoring standards established during and following infusion
- Initiated exclusion criteria being extended to incorporate any use of recreational drugs

Regulatory compliance issues

Study specific documentation
Need for standardisation in practice to ensure research is robust and integrity maintained
Randomisation and un-blinding processes had to be specified

- Drew up Standard Operating Procedures (SOPs) for drug preparation and administration
- Agreed and implemented documentation encompassing study process, sample handling, and collection of study monitoring data
- Ensured all processes and interventions given clear and auditable trail
- Ensured training records in place for all staff involved in study
- Implemented randomisation process to be followed to ensure participant safety while maintaining researcher and participant blinding
- Established secure but accessible location of unblinding code in case of emergency

Logistics

Screening on same day as study visit meant loss of some fMRI slots when participants failed screening
Not feasible for multi user facility to accommodate 90 visits in 12 weeks
Guidelines for sample handling and processing had to be established

- Rescheduled screening to take place several days prior to 1st study intervention to allow for rebooking of replacement participants
- Liaised to receive advance notification of fMRI bookings in order to ensure availability of CRF resources
- Negotiated and implemented more realistic timeframe for study visits
- Drew on specialised clinical experience to establish sample handling, processing centrifuge and storage strategy and to ensure robust data collection.