Post-Marketing Medical Device Study in Venous Leg Ulcer Participants

VCTC Case Study

Overview

- Post-marketing medical device trial of two dressings used for venous leg ulcers (VLU) as standard of care in the UK.
- Study data were needed to support future product reimbursement activities.
- Enrol 40 participants in the UK as a rescue site.
- Participants needed to be treated in specialist VLU clinics and kept in their standard of care treatment throughout the study.

Sponsors
Large UK medical device company

Challenges

- **Standard of Care treatment**
  Participants required standard of care treatment alongside their study treatment, which meant that they couldn't be referred onto a trial site for inclusion.

- **Comparator products**
  The study required participants to be eligible for two standard of care dressings for VLU that was not in-line with care provided at most VLU clinics in the UK.

- **Rapid set-up required**
  The study had been on-going for some time in Columbia, and set-up in Germany and Poland had not been completed after many months.

  The Sponsor needed the study to be completed in a set period to give them the data required for reimbursement activities.

Outcomes

- Positive feedback from participants about being given the opportunity to contribute to research.
- Positive feedback from clinics about the new Central PI model.
- Start-up processes and communication with the Sponsor team ensured approvals were gained within 12-weeks [HH1] of being contracted to the study, and our site team expertise resulted in the acceptance of this new Central PI model by the REC and HRA.
- Central Principal Investigator model allowed a research overlay to be provided to NHS clinics to ensure participants remained in their standard of care whilst being able to participate in the study.
- Over recruitment of our targets, with 42 participants recruited in 4 months.
- Fastest recruiting site globally, with 9 participants recruited per month compared to a global average of 1.25 participants/site/month for other sites.

Tactics

How VCTC overcame these challenges and achieved a successful outcome

Clinic identification

The NiHR identified 6 NHS VLU clinics that had a standard of care treatment pathway in line with what was required by the protocol, and supported the rapid set-up through the relevant R&D Trusts.

Central PI model

VCTC has a first-of-its-kind agreement with the HRA to run a central Principal Investigator model with NHS clinics.

This model sees VCTC acting as a central hub, providing research services to the VLU clinics. The clinics were set-up as satellite sites of VCTC, with our Investigators overseeing the day-to-day trial activities at each of the clinics.

The main VCTC team were responsible for most of the research aspects of the study such as determining eligibility, and entering data into the eDC.

The clinics remained responsible for delivering care to the participants and providing the central VCTC team with the source data from visits.

Responsive and engaged Principal Investigator

- The Principal Investigator on this study, Dr Shah, was fully engaged with the study, made decisions quickly, spoke to the clinics regularly, and was always available for study related questions.
- This ensured that the study was being appropriately managed in the virtual environment.
- We maintained an audit ready delegation of authority log and any questions that required PI input were addressed quickly.

Dedicated study team

Enrolment onto the study was made during the participants routine clinic visits, which meant that time was very short.

This means that in order to be successful, the central VCTC team had to review eligibility information, confirm enrolment of the participant, and complete randomisation to the wound dressing withing 10 minutes of the data being submitted by the clinic team.

Our investigator team worked on a rota basis covering all of the times that the clinics were open, and whilst on shift they focussed 100% on delivering this study.

Digital solutions

All aspects of the study were run using digital solutions, so that everything for the study was available electronically. For example, consent was done in person at the clinics but using Docusign signatures on an iPad, data were collected into electronic forms on an iPad, and we had an electronic Investigator Site File.

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