CONDUCTING A PHASE III CLINICAL TRIAL IN A HOSPICE ENVIRONMENT

Hilary Nailon[1], Juliet Spiller[1], Siwan Seaman[2], Audrey Geary[1], Catherine Adams[3], Kerry Paradowski[2], Chrisanne Gorman[4], Liz Arnold[1], Anne Finucane[1,5], Emma Carduff[1]

[1]*Marie Curie Hospice Edinburgh,* 45 Frogston Road, Edinburgh EH10 7DR. [2]*Marie Curie Hospice Cardiff and the Vale,* Bridgeman Road, Penarth CF64 3YR. [3]*Marie Curie,* 1 Embassy Gardens, London SW11 7BW. [4]*Scottish Cancer Research Network, Edinburgh Cancer Centre*, Western General Hospital, Edinburgh EH4 2XU. [5]*University of Edinburgh*, Clinical Psychology, Teviot Place, Edinburgh EH8 9AG.

Introduction

Clinical trials are considered the gold-standard for the evaluation of interventions in healthcare[1,2].

However, there is a lack of literature on clinical trials within hospice environments, despite evidence that describes multiple benefits reported by trial participants with advanced disease[3].

Here, we report our experience, including barriers and facilitators, of setting up and conducting a multi-centre phase III clinical trial in two Marie Curie hospices with different research infrastructures.

Method

Nov 22 – Jan 23

- Protocol review and identifying key roles within the clinical and research teams.
- Central Marie Curie research governance approval and local approval at each site.
- Communication with key members of the local clinical team to define roles and responsibilities.

Jan 23 – Present

- Management team begin recruitment of trial specific research nurse to coordinate the trial, oversee recruitment and data management.
- Finalising site-specific trial documentation.
- Site Initiation Visits by the trial sponsor to meet local clinical and research staff.
- Preparation and delivery of education sessions delivered by the Research Nurse to the local clinical teams.

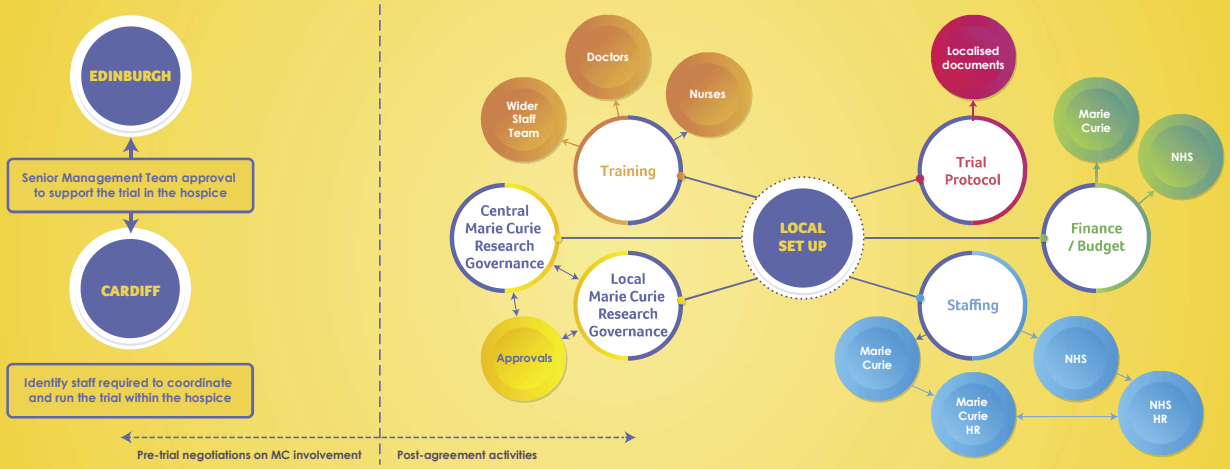

Figure 1: Key setup activities before and after approval of the trial in the two participating centres.

Results

This process has highlighted barriers and facilitators in the following themes: 1) the safety of participants and staff; 2) staff training; 3) communication between research and clinical teams; 4) trial management and 5) solutions required to deal with differences in research resources (i.e., barriers), including staffing constraints, at both sites.

Key timelines: The first site to open recruited five patients in the first six months. The second site recruited one patient in the first week of opening.

Conclusion

- Using a coordinated team approach it has been possible to conduct a clinical trial within two different hospices.
- Good communication from an early stage between research and clinical teams was essential for the successful launch of the trial.
- Because of the existing research infrastructure at one of the sites, local setup proved more straightforward, highlighting the benefit of research staff within the clinical team.
- At the second site, without an existing research infrastructure, successful recruitment was still possible because of good collaboration and support from specialist research staff.

References: [1]Thomas RAB, Aitken EL, Antonelli J, Marson L. How to set up a clinical trial. Postgrad Med J. 2020 Sep;96(1139):564-569. doi: 10.1136/postgradmedj-2019-137379. Epub 2020 Mar 26. PMID: 32217746. [2] Sibbald B, Roland M. Understanding controlled trials: why are randomised controlled trials important? BMJ 1998;316:201. [3] Middlemiss T, Lloyd-Williams M, Laird BJ, Fallon MT. Symptom Control Trials in Patients with Advanced Cancer: A Qualitative Study. J Pain Symptom Manage. 2015 Nov;50(5):642-649.e1. doi: 10.1016/j.jpainsymman.2015.05.009. Epub 2015 May 29. PMID: 26031710; PMCID: PMC4627489.

Contact: Hilary Nailon: hilary.nailon1@mariecurie.org.uk
Marie Curie Hospice Edinburgh, 45 Frogston Road, Edinburgh EH10 7DR.

Marie Curie