Wincott et al. Trials 2015, 16(Suppl 2):P122
http://www.trialsjournal.com/content/16/S2/P122

TRIALS

POSTER PRESENTATION Open Access

Methodology for UK recruitment into a large-scale international clinical trial

Elizabeth Wincott*, Rejive Dayanandan, Richard Haynes, Michael Lay, Martin Landray, Jane Armitage

From 3rd International Clinical Trials Methodology Conference
Glasgow, UK. 16-17 November 2015

Background

Recruitment into long-term trials requires identification and screening of potential subjects and strategies to maximize post-randomization compliance. We describe a successful strategy used for UK recruitment into a large international trial assessing the effect of extended release niacin/laropiprant (ERN/LRPT) on cardiovascular outcomes.

Methods

Ethics and Section 251 of the Health and Social Care Act approval allowed potentially eligible patients to be identified (without consent) from local site's hospital records and invited by a central coordinating office to a local screening appointment.

Following a screening visit and initial run-in phase to standardise background LDL-cholesterol management, those remaining eligible entered an active ERN/LRPT run-in to assess their tolerance of the drug and likely long-term compliance. Participants, if still eligible, were then randomized to ERN/LRPT or placebo.

Results

Electronic records from 89 hospitals allowed 228,391 potential participants to be invited of whom 24,396 (11%) attended a Screening visit. Of the 14,237 entering the active ERN/LRPT run-in, 6202 (44%) withdrew before randomization; the majority (82%) due to adverse effects from ERN/LRPT. Without this active run-in, randomization of the 8035 participants would have been completed in about half the time but adherence to study treatment and completeness of follow-up after randomization would have been substantially worse than the 77% and > 99% achieved respectively, adversely affecting power.

Conclusion

This recruitment method provided a streamlined, cost-effective approach to successful large-scale recruitment. The active pre-randomization run-in ensured that only those able to tolerate the drug were randomized helping to ensure good post-randomization adherence.

Published: 16 November 2015

doi:10.1186/1745-6215-16-S2-P122
Cite this article as: Wincott *et al.*: Methodology for UK recruitment into a large-scale international clinical trial. *Trials* 2015 **16**(Suppl 2):P122.

University of Oxford, Oxford, UK