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Comparing two methods of site initiation for centres recruiting patients into a surgical trial

Submission date
25/04/2013

Recruitment status
No longer recruiting

Registration date
08/05/2013

Overall study status
Completed

Last Edited
19/10/2018

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Randomised controlled trials (RCTs) can be problematic and complicated to set up, and often suffer from problems with slow recruitment; limiting the potential for meaningful conclusions to be drawn from studies. A key problem that has been identified in the setting up phase of RCTs relates to the delays that can occur prior to submission for R&D approval.
Preliminary contact with trial sites prior to R&D application provides the opportunity to discuss the trial rationale and design, finalise local arrangements and obtain any additional information that may be necessary for R&D approval. Two methods of preliminary site initiation have been adopted in surgical trials to date (on-site visits and remote initiation), however the effectiveness of these methods is unclear as similarly long time delays to R&D approval and patient recruitment have been reported across studies despite variations in approach.
This study aims to investigate the cost-effectiveness of these two approaches to preliminary initiation of sites being set up to recruit patients into a multi-centre randomised controlled trial in orthopaedic surgery.

Who can participate?
Sites being set-up to recruit patients into an orthopaedic surgery trial will be included and blinded to their involvement in order to prevent any change in attitudes towards site set up and recruitment. The hospital site of the Chief Investigator and trial sponsor will be excluded from this study as this site is not only involved in recruitment but is substantially involved in setting up the trial in general.

What does the study involve?
At first point of contact, sites will be randomised to receive either on-site initiation visits or remote initiation via email and telephone correspondence. Sites will be randomly allocated on a 1:1 ratio and minimisation will be used to ensure the groups are balanced in terms of important characteristics that may impact on a sites ability to get set up and recruit: 1) whether the principal investigator has previous experience of working on a multi-centre surgical RCT, 2) whether the site has a research nurse in place, 3) the size of the hospital catchment area.
Initiation contact with sites will be standardised using a detailed site initiation checklist to ensure comparability of discussions across trial arms. A detailed record of costs associated with

each trial arm will be kept using the main trial database (e.g. number of telephone calls, emails, visit costs and time).
A range of outcomes will be measured to assess the effectiveness of on-site versus remote initiation, such as time to R&D submission and approval, recruitment and screening activity at sites, and subsequent data collection for recruited patients. The costs associated with each approach will also be examined using information about the researchers time use and travel costs of each trial arm. Research nurses and local PIs opinions and satisfaction with set up processes, recruitment and data collection will also be explored using a follow-up survey.

What are the possible benefits and risks of participating?
Both approaches are commonly used to set up sites in RCTs and we do not anticipate any negative implications for patients as all sites will receive the same amount of training in trial procedures when setting up the site after R&D approval.
Should sites be randomised to the remote initiation group and subsequently the local site Principal Investigator feel that they would benefit from face to face contact to discuss the trial, this will take place and the site will remain in the study and be analysed under the assumptions of intention to treat.
Recruitment at sites will be monitored on an on-going basis by the trial co-ordinators and at regular Trial Management Group meetings. If the trial is not meeting recruitment targets and monitoring indicates substantial differences in recruitment rates at sites in either trial arm, a decision may be taken to end the study so as not to jeopardise patient recruitment in the main trial.

Where is the study from?
Hospital sites from across the UK will be included.

When is the study starting and how long is it expected to run for?
May 2013 until March 2017

Who is funding the study?
The NIHR Health Technology Assessment Programme (HTA), UK.

Who is the main contact?
Laura Jefferson (Trial Co-ordinator)
laura.jefferson@york.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA: 11/36/37

Study information

Scientific Title
A nested randomised controlled trial evaluating the cost-effectiveness of two different methods of site initiation in a surgical trial - remote versus on-site visits

Study objectives
To investigate the costs and effectiveness of providing on-site initiation visits at trial sites (prior to application for research governance approval) on subsequent set up times, recruitment measures, data collection and the costs associated with each approach.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Since this is a methodological study and does not involve research participants in any way, ethical approval was not sought.

Study design
Randomised controlled trial and economic evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Trial methodology

Interventions
Hospital sites will be randomised to one of two forms of site initiation:
1. On-site face to face visits
2. Remote initiation via email and telephone correspondence

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
There is no primary outcome as such and a range of outcomes will be explored descriptively and by trial arm in order to inform the feasibility of undertaking such a comparison across other trials. These include:

Set-up:
1. Time from first contact to R&D submission
2. Time from first contact to R&D approval
3. Time from first contact to set-up meeting prior to recruitment commencing

Recruitment:
1. Number of eligibility forms returned (estimate of screening activity)
2. Proportion of consenting patients out of eligible patients screened
3. Number of patients recruited: Total
4. Number of patients recruited: For the number of months the last site set up has to recruit
5. Time from first contact to time of first recruited patient per site
6. Time from first contact to average time to recruitment per site
7. Time from first contact to time of recruitment of each patient

Data collection:
1. Hospital forms: Proportion returned (after first request and in total)
3. Patient questionnaires: Proportion returned
4. Patient questionnaires: Time to return (after first request and in total)

Secondary outcome measures
No secondary outcome measures.

Overall study start date
01/05/2013

Completion date
31/03/2017

Eligibility

Key inclusion criteria

Hospital sites being contacted to set up to recruit patients into a randomised controlled trial in orthopaedic surgery will be eligible for inclusion.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
At least 17 sites will be included in this evaluation

Key exclusion criteria
The hospital site of the Chief Investigator and trial sponsor will be excluded.

Date of first enrolment
01/05/2013

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of York
Lower Ground Floor ARRC Building
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details

Leicester General Hospital
Leicester
England
United Kingdom
LE5 4PW

Sponsor type
Hospital/treatment centre

Website
http://www.leicestershospitals.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK) grant ref: 11/36/37

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No