20/2010

NHS

National Research Ethics Service

Derbyshire Research Ethics Committee
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29 April 2010

Professor Sarah Lamb
Director, Warwick Clinical Trials Unit
University of Warwick
Warwick Clinical Trials Unit
University of Warwick
Gibbet Hill Road, Coventry
CV4 7AL

Dear Professor Lamb

Study Title: **Prevention of Fall Injury Trial**
REC reference number: **10/H0401/36**
Protocol number: **1**

The Research Ethics Committee reviewed the above application at the meeting held on 20 April 2010. Thank you to Dr Chris Bridle for attending to discuss the study.

Ethical opinion

1. The Committee asked about the consent process, and if consent is being taken for treatment. Dr Bridle explained that practices will be asked to adopt an arm of the study and that participants will receive clinical care with all components available on the NHS.
2. The Committee asked if there may be variation in the standard of care. Dr Bridle stated that a survey had been done and variation noted. Participants will only be recruited from practices that can provide services. He went on to say that services can be fragmented and are not always within a defined location.
3. The Committee asked if there is a standardised approach from practices. Dr Chris Bridle informed the Committee that a number of options will be looked at and that data on fractures will be provided from PCTs.
4. The Committee asked why HES statistics are being used if they don't identify the population. Dr Bridle agreed that the statistics can't identify individuals but can give aggregate level data, which will even out over the arms of the trial.
5. The Committee asked if the participants will have barriers to accessing services and if the research team had though of providing transport. Dr Bridle stated that community transport has been considered. The need for transport provision should be identified by the pilot.
6. The Committee pointed out to Dr Bridle that the questionnaire contained a section numbering error. Dr Bridle agreed to correct the document.
7. The Committee asked why the Participant Information Sheet (PIS) does not mention falls. Dr Bridle informed the Committee that this had been discussed, but the researchers have decided to use positive terminology. Research has been done on framing messages and positive messaging works.

The members of the Committee present gave a favourable ethical opinion of the above

research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

1. The following additions/revisions are required on the Participant Information Sheet (PIS):
    a. Under the heading 'What will I be asked to do if I take part in the study' more information should be provided about the trial arms and measurements of cognitive ability.
    b. State that the study has been reviewed by the Derbyshire Research Ethics Committee.
2. The following additions/revisions are required on the consent form:
    a. Point 1 should be complete with the version and date of the current PIS.
    b. The document should include the mandatory regulatory authorities paragraph:
    I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [company name if applicable], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
3. The section number heading error in the questionnaire should be corrected.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering Letter		08 April 2010
REC application	40999/112157/1/499	08 April 2010
Protocol	1	
Participant Information Sheet	1	01 April 2010
Participant Consent Form	1	01 April 2010
Letter of invitation to participant	1	01 April 2010
GP Invitation Letter	1	01 April 2010
Investigator CV		01 April 2010
Evidence of insurance or indemnity		17 July 2009
Questionnaire: Balance and Mobility for Older People: Research Study	1	01 April 2010

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H0401/36	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

pp L Gregory

Mr Robert Johnson
Chair

Email: lisa.gregory@nottspct.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
"After ethical review – guidance for researchers" SL-AR2

Copy to: *Dr Peter Hedges, University of Warwick*
R&D office for NHS care organisation at lead site - University Hospitals of Coventry and Warwickshire