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NHS

National Research Ethics Service

Nottingham Research Ethics Committee 2
1 Standard Court
Park Row
Nottingham
NG1 6GN

Telephone: 0115 9123344
Facsimile: 0115 9123300

16 FEB 2009

09 February 2009

Professor Philip Bath
Division of Stroke Medicine
Clinical Sciences Building, City Hospital
Nottingham
NG5 1PB

Dear Professor Bath

Full title of study: **Determining the potential of ambulance-based randomised controlled trials in patients with hyperacute stroke; assessment of GTN in lowering blood pressure**
REC reference number: **09/H0408/5**
Protocol number: **1.1**
EudraCT number: **2007-004766-40**

The Research Ethics Committee reviewed the above application at the meeting held on 26 January 2009. Thank you for attending to discuss the study.

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Protocol	1.1	01 July 2008
Investigator CV		06 October 2008
Application	AB/134957/1 & C/134957/219893/1	06 January 2009
Letter of Response to Unfavourable Opinion letter		17 December 2008
Unfavourable Opinion letter from Nottingham 2 REC		05 March 2008
Participant Consent Form: after assent form	1	01 November 2007
Participant Consent Form	1.0	01 November 2007
Participant Information Sheet: Relatives - to continue in trial once initial consent has been taken by paramedic	1.1	05 September 2006
Participant Information Sheet: to continue in trial once initial consent has been taken	1.0	01 November 2007
Evidence of Insurance		05 August 2008
GP/Consultant Information Sheets	1.0	01 November 2007
Letter from Sponsor		18 December 2008
Request form for authorisation from the MHRA (Annex 1 to ENTR/CT1) without enclosures		

Provisional opinion

- For patients who can consent, consent will be gained. A brief description of the trial will be read to the patient in the ambulance and verbal consent will be taken for the patient to receive trial medication in the ambulance. Once in hospital a full patient information sheet will be given to the patient and an investigator will be available to answer questions. The hospital investigator will take written consent.
- If a patient cannot consent and a relative is available verbal assent will be gained from the relative in the ambulance to receive study medication in the ambulance and written assent will be obtained from the relative on behalf of the patient once in hospital. A 'relative information sheet' will be given and the hospital investigator will be available to answer questions.
  If no relative is available and the patient cannot give consent the paramedic would be able to get assent for emergency treatment over the telephone from an independent physician.
- The paramedics will confirm whether they are likely to have had a stroke by using an assessment designed for non-doctor health care workers called the FAST test. This assesses whether a person has face or arm weakness or speech difficulty which are very common in stroke.
- Data Monitoring Committee minutes are available on the website

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

The Committee delegated authority to confirm its final opinion on the application to the Chair.

Further information or clarification required

1. If the patient fits the criteria the paramedics will read out a brief pre-prepared script and the patient will then decide if they are happy to enter the first stage of the trial. The Committee requested a copy of the script.
2. The Committee requested a written record of the de-briefing service
3. The Committee requested a paper copy of the latest Data Monitoring Committees minutes
4. The Committee requested the following changes/amendments to the Patient Information Sheet.
   a. Under the section headed 'What will happen to me if I take part?' 6th paragraph 'You will be contacted 3 months after your stroke to return for a visit ...' ' or receive a phone call' should be included
   b. The section headed 'Harm' should be re-written for the patient not relative.
5. Point 1 of the Consent Form should refer to the date and version number of the new Information Sheet.
6. An Assent form for the paramedic to obtain assent for emergency treatment over the telephone from an independent physician should be submitted

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 26 May 2009.

Membership of the Committee

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

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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.

09/H0408/5	**Please quote this number on all correspondence**

Yours sincerely

Dr Martin Hewitt/Ms Linda Ellis
Chair/Research Ethics Service Manager and Co-ordinator

Email: linda.ellis@nottspct.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments.*

Copy to: *Mr Paul Cartledge*
R&D Department for NHS care organisation at lead site NUH (via email)

Nottingham Research Ethics Committee 2

Attendance at Committee meeting on 26 January 2009

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Deborah Annesley-Williams	Consultant Neuroradiologist	Yes	
Ms Karen Asher	Secretary	No	
Dr Frances Game	Consultant Physician	No	
Dr Diane Gilmore	Medical Sociologist	Yes	
Mr Richard Greenhow	Medical Student	No	
Dr Martin Hewitt	Consultant Paediatrician Oncologist	Yes	
Mrs Sheila Hodgson	Clinical Trials Pharmacist	Yes	
Mrs Anita Hughes	Research Midwife	No	
Dr David Lott	Pharmaceutical Physician	Yes	
Mr Jonathan Mitchell	Barrister	No	
Mrs Ruth Musson	Pathology Specialist Nurse	Yes	
Mrs Linda Reynolds	Occupational Therapist	Yes	
Dr Simon Roe	Consultant Nephrologist	Yes	
Mr Glen Swanwick	Lay Member	Yes	
Ms Margret Vince	Lay Member	Yes	
Reverend Paul Weeding	Chaplain	No	
Miss Emma Wilkinson	Staff Nurse	Yes	