National Research Ethics Service
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RK/STA/hph

10 August 2009
(amended 17 August 2009)

Dr I G Williamson
Senior Lecturer
University of Southampton
Primary Medical Care
Aldermoor Close
Southampton
Hampshire
SO16 5ST

Dear Dr Williamson

Study Title: **An open randomised study of autoinflation in 4-11 year old school children with otitis media with effusion (OME) in primary care.**

REC reference number: **09/H0504/75**
Protocol number: **2**
EudraCT number:

Thank you for your letter of 06 August 2009, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Alternate Vice-Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, 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).

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.

It is the 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 final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
GP Information for Pilot Study	1	06 November 2008
Draft Letter for Invitation to Screening: Parent Letter 2	1	06 November 2008
Appendix 2: Participant flow through Study	1	
Appendix 1: Flow Chart	1	17 March 2009
Participant Consent Form: Parent	1	06 November 2008
GP/Consultant Information Sheets	1	06 November 2008
Covering Letter		29 April 2009
Application		29 April 2009
GP Interest Fax Back Form	1	06 November 2008
Patient Flow	1	06 November 2008
Questionnaire: Initial Appointment Form	1	06 November 2008
Questionnaire: HUI- 3 Months	1	06 November 2008
Questionnaire: HUI - Baseline	1	06 November 2008
Questionnaire: Parent: 3 Month Measures (OM8-30)	1	06 November 2008
Questionnaire: Parent: Baseline Measures (OM8-30)	1	06 November 2008
Compliance Reward Chart	1	06 November 2008
Diary 2	1	06 November 2008
Diary 1	1	06 November 2008
Questionnaire: 1 Month Measures Form	1	06 November 2008
Questionnaire: 2-4 day post baseline compliance check + follow-up appointment if necessary	1	06 November 2008
Questionnaire: Baseline About you and your child	1	06 November 2008
Questionnaire: Baseline Measures Form	1	06 November 2008
Questionnaire: First Screening Form	1	06 November 2008
Questionnaire: Health Resource Use at 6 Months	1	06 November 2008
Questionnaire: 3 Month Measures Form	1	06 November 2008
Compensation Arrangements		23 April 2009
Letter from Sponsor		23 April 2009
Investigator CV		20 April 2009
Response to Request for Further Information		23 July 2009
Participant Consent Form: Assent	2	25 June 2009
Participant Information Sheet: 4-5 year olds	2	25 June 2009
Protocol	2	03 July 2009

Draft Letter for Invitation to Screen: Parent Letter 1	3	05 August 2009
Response to Request for Further Information		06 August 2009
Participant Information Sheet: Patient (6-11 years old)	3	05 August 2009
Participant Information Sheet: Parent	3	05 August 2009

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.

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 [redacted]

09/H0504/75 **Please quote this number on all correspondence**

Yours sincerely

Professor R King
Alternate Vice-Chair

Email: [redacted]

Enclosures: "After ethical review – guidance for researchers" SL- AR2 for other studies

Copy to: Dr Martina Prude
University of Southampton

Ethics committee approval and amendments to the protocol

Amendment number	Amendment date	Summary of changes
Ethics committee approval	10 August 2009	
Amendment 1 (minor)	27 August 2009	• Minor changes to consent form •
Amendment 2	29 Sept 2010	• Protocol changes: clarification of randomization procedures •
Amendment 3	29 March 2010	• Addition of a pilot study survey for nurses to gain feedback for the main trial.. •
Amendment 4	7 April 2011	• New exclusion criteria (recurrent nosebleeds) • Web-based randomization • Improved version of parent questionnaire • Minor changes to protocol, invitation letters, information sheets and questionnaires
Amendment 5	6 October 2011	• Changes to CRFs and questionnaires following successful pilot • Additional questionnaires and CRFs (Heath Resources and Costs to Parents) • Minor changes to protocol to add clarity
Amendment 6	31 May 2012	• Minor changes to the invitation letter to enable use of DocMail (not used) • Parent Information card for the TADAST web hearing test • Poster for Waiting Room
Amendment 7	12 July 2012	• Agreement for over-recruitment to a maximum of 350 children • Approval for re-invitation of children from previous season
Amendment 8	14 August 2012	• Detailed methods of qualitative evaluation- parents and nurses
Amendment 9	9 May 2013	• 12 month notes review
Amendment 10	17 March 2014	• Detailed methods of qualitative evaluation – GPs