



Health Research Authority

NRES Committee South West - Central Bristol

Bristol Research Ethics Committee Centre
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05 February 2013

Dr Alastair Hay
University of Bristol
Canyng Hall, 39 Whatley Road
Bristol BS8 2PS

Dear Dr Hay

Study title: What is the clinical and cost effectiveness of oral steroids in the treatment of acute lower respiratory tract infection (LRTI)? A placebo controlled randomised trial
REC reference: 12/SW/0180
Protocol number: UoB1581
EudraCT number: 2012-000851-15
Amendment number: 1
Amendment date: 22 January 2013
IRAS project ID: 102138

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Summary of amendments to protocol and consent form		
Case Report Form draft	0.13	13 December 2012
Symptom diary peak flow meter instructions		13 December 2012
Primary care notes review	0.11	27 November 2012
Sample Diary/Patient Card	11. Symptom Diary	13 December 2012

Participant Consent Form	1.3	13 December 2012
Protocol	1.2	13 December 2012
European Commission Notification of Substantial Amendment Form	1	22 January 2013
Covering Letter		22 January 2013
Sponsor confirmation		01 February 2013

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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.

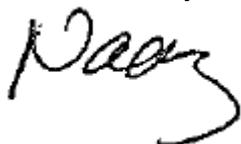
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

12/SW/0180:	Please quote this number on all correspondence
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Yours sincerely



pp. **Dr Margrid Schindler**
Vice Chair

E-mail: nrescommittee.southwest-bristol@nhs.net

Enclosures: List of names and professions of members who took part in the review

*Copy to: Mrs Rachel Avery, Avon Primary Care Research Collaborative
Dr Birgit Whitman, University of Bristol*

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Attendance at Sub-Committee of the REC meeting in correspondence

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mr Trevor Beswick	Director - SW Medicines, Information & Training	Expert
Dr Margrid Schindler	Consultant Senior Lecturer	Expert

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Naazneen Nathoo	Coordinator