A double-blind randomised placebo-controlled trial of topical nasal steroids in 4-11 year old children with persistent bilateral Otitis Media with Effusion (OME) in primary care

Submission date	Recruitment status No longer recruiting	Prospectively registered		
08/10/2003		☐ Protocol		
Registration date 09/10/2003	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
05/01/2010	Ear, Nose and Throat			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Ian Williamson

Contact details

Primary Medical Care
University of Southampton
Aldermoor Health Centre
Aldermoor Close
Southampton
United Kingdom
SO16 5ST
+44 (0)23 8024 1071
igw@soton.ac.uk

Additional identifiers

Protocol serial number

HTA 01/72/02

Study information

Scientific Title

Acronym

GNOME

Study objectives

Otitis Media with Effusion affects about 85% of children by the age of 10 and can lead to hearing loss and other problems such as speech delay, educational and behavioural impairments. Referral for surgery may rise in the UK when the MRC TARGET findings are published. Presently there are no effective temporizing medical managements for the majority of children with this condition, and there is a need to find alternatives to antibiotics.

The majority of effusions are associated with virus infections, and do not need treatment, so the children identified in practices will enter a 3 month period of watchful waiting before randomization. Children will be identified through case finding and targeted by audit on the basis of risk factors, before being invited for tympanometry, by validated and fully trained research nurses.

Only persistent cases on both sides (3 months) will be included. The intervention is of a topical intranasal steroid or placebo once a day for 3 months. We will gather baseline and outcome data on the major effect modifiers and perform Pure Tone Audiometry and microtympanometry. Outcomes will be at 1, 3, and 9 months, and will include the necessary measures for a health economic evaluation of effectiveness with modeling in analysis. In addition we will include the OM7-27 questionnaire developed by the MRC as a sensitive and specific measure of change and quality of life.

Protocol can be found at http://www.hta.ac.uk/protocols/200100720002.pdf More details can be found at http://www.hta.ac.uk/1352

Please note that, as of 15 January 2008, the anticipated start and end dates of this trial have been updated from 1 June 2003 and 31 August 2007 to 1 September 2003 and 29 February 2008, respectively.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Double blind randomized placebo controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Otitis media with effusion - "glue ear"

Interventions

- 1. Topical nasal steroid spray mometasone furoate + standard clinical management
- 2. Placebo nasal spray + standard clinical management

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

mometasone furoate

Primary outcome(s)

The primary end-point will be differences in rates of clearance of bilateral effusions in children (not ears) between treated and placebo arms at 1 month. We will be using microtympanometric assessment and the modified Jerger classification of tympanograms.

Key secondary outcome(s))

Not provided at time of registration.

Completion date

29/02/2008

Eligibility

Key inclusion criteria

Children aged 4-11 with bilateral otits media with effusion (B+B or B+C2 tympanograms) after 3 months of watchful waiting

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 years

Upper age limit

11 years

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/09/2003

Date of final enrolment

29/02/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Primary Medical Care

Southampton United Kingdom SO16 5ST

Sponsor information

Organisation

University of Southampton (UK)

ROR

https://ror.org/01ryk1543

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/12/2009		Yes	No
Other publications	HTA monograph	01/08/2009		Yes	No