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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
08/10/2003

Recruitment status
No longer recruiting

Registration date
09/10/2003

Overall study status
Completed

Last Edited
05/01/2010

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
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.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/09/2003

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

Age group
Child

Lower age limit
4 Years

Upper age limit
11 Years

Sex
Not Specified

Target number of participants
Not provided at time of registration.

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
England

United Kingdom

Study participating centre
Primary Medical Care
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
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Sponsor type
Government

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ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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