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Study of autoinflation in 4-11 year old school children with glue ear

Submission date	Recruitment status	[X] Prospectively registered
05/05/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/06/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/06/2016	Ear, Nose and Throat	

Plain English summary of protocol

Background and study aims
Otitis media with effusion (OME) is usually known as glue ear. It is a collection of sticky fluid behind the ear drum. It is the commonest chronic condition of childhood (80% affected at some point) and also the commonest reason for childhood surgery. The already very high incidence (10-30%) is likely to increase further from influenza outbreaks and a rise in the recent birth rate. It is often slow to resolve and may progress or recur, causing deafness. If it does not resolve, surgical treatment with grommets is often necessary. Glue ear can therefore have a significant impact on the child's life and development. Approximately 200,000 children are seen each year in UK general practice and community settings. Current treatments in this setting do not work well, cost money and have harms to society e.g. antibiotic resistant bacteria. There is emerging evidence that the proportion of children getting better naturally could increase substantially if a technique called autoinflation was used. This involves the child blowing up a balloon through each nostril three times a day (Otovent device). This corrects negative pressures behind the eardrum and speeds up recovery. In most cases it is envisaged that it will stop the condition progressing and avoid the need for surgery (grommets).

Who can participate?
4-11 year old school children with glue ear from 40 General Practices.

What does the study involve?
The study will be led by fully trained research nurses who will help identify children with ear problems. These children will be screened using a painless ear probe technique (tympanometry) to confirm the diagnosis accurately. With parental consent, affected school children will be shown the technique of blowing through the nose into a purpose designed small tube with a balloon on the end. Then they will randomly be allocated to use the Otovent immediately or to wait for 3 months to see if the glue ear resolves by itself. The main measure of the study will be how many children in each group no longer have glue ear after 1 month (or 3 months). At the 3 months follow-up, those children not previously offered the Otovent device (i.e. those receiving just standard care) and who are not better, will be given the opportunity of using the new intervention. Follow-up will be up to 6 months in total.

What are the possible benefits and risks of participating?
The study will be carried out in accordance with clinical trial ethical practice guidelines. The investigators are experienced in running studies involving children. There are no known side effects from use of Otovent but adverse events will be recorded. Child/public involvement will be encouraged and results important to parents (e.g. experience of using the device, time off work) are included in the study.

Where is the study run from?
40 General Practices

When is the study starting and how long is it expected to run for?
There will be an initial study (pilot) over 12 months and a main study over 36 months. Overall the study is expected to last from September 2011 to August 2014

Who is funding the study?
The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme

Who is the main contact?
Dr Ian Williamson
igw@soton.ac.uk

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

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

Acronym
AIRs

Study objectives
Is a standard manufactured autoinflation device (Otovent®) an effective treatment for OME ('glue ear') in children in an National Health Service (NHS) primary care setting?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/090127
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0014/53105/PRO-09-01-27.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Southampton B, 10/08/2009, 09/H0504/75

Study design
Open randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Otitis media with effusion (OME)

Interventions
Autoinflation
Autoinflation is performed using a purpose manufactured device (Otovent®) as supplied to the

trial by Kestrel Medical Ltd. Poole, Dorset. One standard pack contains the nasal tip- a safe spherical connecting device made of plastic and five quality checked latex balloons. Packs will be provided to those randomised to the immediate autoinflation treatment group. One pack covers 1 month of treatment due to decreasing elasticity of each balloon over about a weeks use. All children with a residual B tympanogram at 1 month will be offered two further standard packs to cover two further months of treatment. Uptake will be recorded for concordance/compliance considerations.

The child will be instructed to inflate the balloon once via each nostril in the morning, after school, and at bedtime (x6 total). A sticker book diary/wall chart will be provided for the children to encourage participation. All children will receive usual clinical care, and the intervention will be in addition to this. We intend to use practical delivery advice from other relevant trials e.g. use of parents to demonstrate the method, use of the extended Valsalva manoeuvre and or Politzer equivalent, with use of step-wise techniques for very young children to help them to actually blow air through the nozzle first, etc. The training and support element, whilst evidence-based and making use of secondary care expertise, is actually very simple, and encapsulated in a brief written protocol and manual which could be readily implemented by a nurse during a single consultation.

For more details please visit www.gluear.co.uk

Standard Care
The standard care of children presenting in primary care with suspected ear effusions or glue ear consists of full assessment using history and otoscopy. Advice is given about practical management of the condition and any concerns addressed. Patient information sheets may be used and tips about managing suspected hearing loss can be found on relevant websites e.g. Deafness research UK. Many general practitioners (GPs) usual treatment is for antibiotic courses with or without decongestants while others adopt a no treatment policy for a limited period. Children are invited back for further assessment at four weeks with a further follow up invitation at 3 months. Where there are over riding concerns about the child e.g. about significant physical ill-health, hearing, speech, or development impairment (i.e. significant impairment to quality of life) referral to ear, nose, thraot (ENT) specialist is made. In the trial all children will receive tympanometry and hearing assessments as part of the active monitoring (watchful waiting) standard care package.

Intervention Type
Device

Primary outcome measure
1. Tympanometric resolution in at least one affected ear per child at 1 month, defined as conversion of the B-type highly predictive of effusion to either an A1 or C1 type i.e. back to normal pressures
2. In addition, study specific questionnaire at baseline, 1 and 3 months, weekly diaries up to 3 months (to record days with reported hearing loss and earache and also include less documented adverse events e.g. vertigo, as well as recording periods of remission and recurrence)

Secondary outcome measures
1. Tympanometric resolution in at least one affected ear per child at 3 months, defined as conversion of the B-type highly predictive of effusion to either an A1 or C1 type i.e. back to normal pressures

2. OMQ-14a functional health status measure, Health Utilities Index, study specific questionnaire of NHS resource use - all self-administered at baseline and 3 months, plus a study specific questionnaire on health resource use including recurrence, referral etc at 6 months.
3. Short study-specific questionnaires at baseline, 1 and 3 months to evaluate compliance, positives/negatives of device. Record of nurse assessments at 1 and 3 months.

Overall study start date
01/09/2011

Completion date
31/08/2014

Eligibility

Key inclusion criteria
1. Aged 4-11 years and attending school at the time of the first planned tympanometric screen (To be able to reliably perform the technique and have a greater theoretical chance of cure)
2. A relevant notes recorded history of recent and/or recurrent otitis media symptoms (defined as within the last year) or ear related problems in the previous year (e.g. suspected hearing loss, slow speech development etc), or a guardian denotes a concern in one or more OME related symptom domains on the screening invitation letter symptom check list (in the targeted 4 to 7 years of age and seasonal high risk of OME groups)
3. Tympanometric confirmation in a child of at least one B tympanogram (using the modified Jerger classification). This has an approximate 90% positive predictive value of an effusion being present i.e. cases of unilateral or bilateral OME.

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
294

Key exclusion criteria
1. Children who need early referral as judged clinically, to include those known rarer cases with high risk of recurrence: Down's syndrome, cleft palate, kartagener's syndrome, primary ciliary dyskinesia, immunodeficiency states, etc.
2. Four year old children not attending school at the time of screening, or children deemed by the nurse unable to comply with the technique of autoinflation

3. At study entry, children with a grommet already in place in an ear drum, or where the child has been referred or listed for ear surgery
4. Latex allergy (balloons are latex)
5. A recent nose bleed in the past three weeks or more than one episode of nose bleeding over the past 6 months

Date of first enrolment
01/09/2011

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Southampton
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Research Governance Office
George Thomas Building 37
Room 4055
University of Southampton
Highfield
Southampton
England
United Kingdom
SO17 1BJ
+44 (0)23 8059 5058
rgoinfo@soton.ac.uk

Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	01/09/2015		Yes	No
Results article	results	22/09/2015		Yes	No
HRA research summary			28/06/2023	No	No