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A controlled trial of Probiotics in the prevention of episodes of otitis media in general practice

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/10/2017	**Condition category** Ear, Nose and Throat	[_] Individual participant data [_] Record updated in last year

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
N0230131783

Study information

Scientific Title
A controlled trial of Probiotics in the prevention of episodes of otitis media in general practice

Acronym
PIPO

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South West Hampshire LREC (UK), 01/09/2003, ref: 174/03/t

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Ear, Nose and Throat: Otitis media

Interventions
A number of GP practices will recruit patients over 2 winters. From the participating practices computer records, children most at risk of several recurrences over the winter months based on previous attendance with otitis media and recorded ear or ear problems. Parents and children will be invited by their GPs to attend special 'surgeries' run by the 4th year student/GP and sent a specifically designed self help leaflet and other information. After informed consent procedures patients will be randomised by using random number sequences to produce coded blocks of 4 which contain either active treatment or placebo. The probiotics lactobacillus and bifdobacteria and placebo used are currently under trial at Addenbrokes for gastrointestinal (GI)

infections. Parents will attend for a second interview and completion of trial materials after 3 months. Stool samples will be collected at the beginning and end of the trial to compare the effect on bowel flora.

Intervention Type
Other

Primary outcome measure
Reported episodes of recurrent significant otalgia difference in proportions over 3 months measured by questionnaires

Secondary outcome measures
1. Otitis media episodes in medical records change in specified outcome measure OM7-27 continuous variable score in 5 clinically important domains
2. To evaluate compliance issues for once daily, 3 month course in this context
3. Description of change in stool microbiology

Overall study start date
01/09/2003

Completion date
31/05/2008

Eligibility

Key inclusion criteria
Children aged 6 months to 11 years with a notes recorded episode of acute otitis media over the previous 12 months or an episode of any other specified ear problem

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
11 Years

Sex
Both

Target number of participants
Added 17/07/2008: 300

Key exclusion criteria
Children will be excluded if they have an allergy to either product or those with failure to thrive

Date of first enrolment
01/09/2003

Date of final enrolment
31/05/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Southampton
Southampton
United Kingdom
S016 5ST

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
c/o Dr Martina Prude (Research Governance Manager)
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Sponsor type
University/education

Website
http://www.soton.ac.uk

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
West Hampshire Consortium (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