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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Ian Williamson

#### Contact details

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## Additional identifiers

## Protocol serial number

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

### Study type(s)

Prevention

#### 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(s)

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

#### Key secondary outcome(s))

- 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

#### Completion date

## **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** 

#### Healthy volunteers allowed

No

#### Age group

Child

## Lower age limit

6 months

#### Upper age limit

11 years

#### Sex

All

#### 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

United Kingdom

England

## Study participating centre University of Southampton

Southampton United Kingdom S016 5ST

# Sponsor information

### Organisation

University of Southampton (UK)

#### **ROR**

https://ror.org/01ryk1543

# Funder(s)

## Funder type

Government

#### **Funder Name**

West Hampshire Consortium (UK)

## **Results and Publications**

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?

Participant information sheet 11/11/2025 No Yes