Randomised trial of pragmatic strategies to manage otitis media in primary care

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
23/01/2004		[X] Results		
Last Edited	Condition category	[] Individual participant data		
29/11/2013	Ear, Nose and Throat			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Paul Little

Contact details

Primary Medical Care Aldermoor Health Centre Aldemoor Close Southampton United Kingdom SO15 6ST +44 (0)2380 241050 pmc1@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SPGS784

Study information

Scientific Title

Study objectives

To determine the pragmatic outcomes of commonly used management strategies for acute red ear in primary care

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised 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

Ear, nose and throat diseases: Ear, nose and throat diseases

Interventions

Course of amoxycillin (125 mg tds 1 week) or course of amoxycillin on request after 72 hrs

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Symptom resolution, analgesia use, antibiotic use, fever resolution, complication rate, satisfaction with treatment, return rate, typanometry, referral to ENT

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/1996

Completion date

01/12/2000

Eligibility

Key inclusion criteria

240 children aged 6 months to 10 yrs with acute painful red ear.

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Months

Upper age limit

10 Years

Sex

Not Specified

Target number of participants

240

Key exclusion criteria

Toxicity, previous antibiotic treatment for otitis media in last 2 weeks, serious chronic disorders, complications from previous attacks

Date of first enrolment

01/10/1996

Date of final enrolment

01/12/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Primary Medical Care

Southampton United Kingdom SO15 6ST

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Executive South East

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 summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/02/2001		Yes	No
Results article	follow-up results	01/03/2006		Yes	No