

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

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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Months

Upper age limit

10 Years

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Primary Medical Care

Southampton

United Kingdom

SO15 6ST

Sponsor information

Organisation

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

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East

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?
Results article	results	10/02/2001		Yes	No
Results article	follow-up results	01/03/2006		Yes	No