

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

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
23/01/2004	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
23/01/2004	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> 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

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

Study design

Randomised controlled trial

Primary study design

Interventional

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, typanometry, 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