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

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[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

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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 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