Antibiotics for acute otitis media in children less than 2 years of age.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26781

Source
NTR

Brief title
Trial with amoxicillin and placebo for AOM

Health condition

acute otitis media in general practice, antibiotics, placebo, infants

acute middenoorontsteking in huisartsenpraktijk, antibiotica en placebo, kinderen onder de 2 jaar.

Sponsors and support

Primary sponsor: Julius Center for Health Sciences and Primary Care, UMC Utrecht
Source(s) of monetary or material Support: Netherlands Organisation for Scientific Research (grant no 904-58-074)

Intervention

Outcome measures

Primary outcome

Persistent symptoms at day 4, assessed by the doctor and defined as persistent earache,

fever, crying or being irritable

Secondary outcome

- Clinical treatment failure at day 11

- Duration of fever or/of pain/crying

- The mean number of doses of analgesics given

- The percentage of children with middle ear effusion at 6 weeks, 3 months and 6 months

- Adverse effects

Study description

Background summary

This trial was planned to see what the effectiveness was of antibiotic treatment in childeren under 2 years of age with acute otitis media in general practice. 7-8 children in this age-group needed to be treated with antibiotics to improve symptomatic outcome at day 4 in one child.

Study objective

Antibiotics might have more effect in the children less than 2 years of age.

Study design

Evaluation at 4 days, 11 days, 6 weeks, 3 months and 6 months.

Further first 10 days a diary.

Intervention

Amoxicillin suspension 40mg/kg/day in three divide doses for 10 days or placebo suspension.

Contacts

Public
R.A.M.J. Damoiseaux

Utrecht
The Netherlands
Scientific
R.A.M.J. Damoiseaux
Utrecht
The Netherlands

Eligibility criteria

Inclusion criteria

1. Children aged 6 months to two years with acute otitis media in general practice

Exclusion criteria

1. Antibiotic treatment in de preceding 4 weeks

2. Allergy to amoxicillin

3. Compromised immunity

4. Craniofacial abnormalities

5. Down's syndrome

6. Being entered in this study before.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-1996
Enrollment:	160
Type:	Actual

Ethics review

Positive opinion

Date:	29-08-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1365
NTR-old	NTR1426
Other	: METC, UMC Utrecht: I93-63
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

- Damoiseaux RAMJ, van Balen FAM, Hoes AW, de Melker RA. Antibiotic treatment of acute otitis media in children under two years of age: evidence based? Gr J Gen Pract 1998;48:1861-4.

- Damoiseaux RAMJ, van Balen FAM, Hoes AW, Verheij TJM, Melker RA. Primary care based randomised, double blind trial of amoxicillin versus placebo for acute otitis media in children aged under 2 years. BMJ 2000;320:350-4.

- Damoiseaux RAMJ, Sanders LAM, van Balen FAM, Rijkers GT. Sibling history of recurrent acute otitis media correlates with low IgG2 anti-pneumococcal polysaccharide antibody levels. Pediatr Infect Dis J 2000;19:176-7.

- Damoiseaux RAMJ, van Balen FAM. Duration of clinical symptoms in children under two years of age with acute otitis media. Eur J Gen Pract 2000;6:48-51.

- Damoiseaux RAMJ, Rovers MM, van Balen FAM, Hoes AW, de Melker RA. Long-term prognosis of acute otitis media in infancy: determinants fo recurrent acute otitis media and persistent middle ear effusion. Fam Pract 2006;23:40-5.