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To evaluate whether a three days course of high doses of amoxicillin in the treatment of pneumonia in children is better compared to standard treatment with co-trimoxazole for five days

Submission date 19/05/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 03/06/2010	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 03/06/2010	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

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
947

Study information

Scientific Title
Efficacy of short course high-dose amoxicillin in the treatment of non-severe community acquired-pneumonia in children: A double-blind, randomised controlled trial

Acronym
HAT

Study objectives
We hypothesised that the treatment failure in community acquired non-severe pneumonia (defined by WHO using respiratory rates) or in community acquired non-severe radiological pneumonia (defined by WHO Radiology Working Group) will be lower in children randomised to twice daily three-day oral amoxicillin 90 mg/kg-per-day (high-dose amoxicillin) compared to five-day standard dose co-trimoxazole (standard therapy).

We also hypothesised that carriage of non-susceptible pneumococci to co-trimoxazole will be lower in children treated with high-dose amoxicillin compared to standard therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Gambia Government / MRC Laboratories Joint Ethics Committee approved on the 23rd of June 2003

Study design
Two arm randomized double blind single centre clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Community acquired pneumonia in children

Interventions
Children randomised to high-dose amoxicillin received amoxicillin in 45 mg/kg/dose twice daily (maximum daily dose 2000 mg/day) for three days, followed by placebo twice daily for two days. Children randomised to co-trimoxazole received trimethoprim in 4 mg/kg/dose plus sulphamethoxazole in 20 mg/kg/dose twice daily for 5 days.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Treatment failure:
1.1. 3 days after enrolment there was no improvement

or
1.2. within 5 days after enrolment, the study drug was changed to another antibiotic, severe pneumonia or very severe disease develops, or death occurs.
All children were assessed by nurses on days 3 and 5 post-enrolment. Treatment failures were confirmed by study pediatricians.

Key secondary outcome(s))
1. Relapse:
Reappearance of signs of non-severe pneumonia or appearance of signs of severe pneumonia or very severe disease by day-14 post-enrolment after being declared as cured on day-5 post-enrollment. All children were assessed by nurses on days 5, 14 and 28 post-enrolment for evaluation of clinical outcomes.
2. Compliance:
Proportion of children given full prescribed dosage (this was assessed by measuring left-over trial antimicrobials in the bottles on days 3 and 5).
3. Carriage rate of co-trimoxazole non-susceptible pneumococci on day-28 post-enrollment.
Nasopharyngeal swab (NPS) for culture and sensitivity to antimicrobials was collected on days 0 and 28 of enrolment.

Completion date
02/06/2006

Eligibility

Key inclusion criteria
1. Aged 2 to 59 months
2. Either sex
3. Nutritional status: Weight-for-height > 70% of National Center for Health Statistics (NCHS) reference without oedema
4. Non-severe pneumonia according to WHO definition: if the child has fast breathing with cough or difficult breathing and there is no chest indrawing or other danger signs

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Having severe pneumonia or very sever disease or if needs oxygen
2. Needed antibiotic, steroid, theophylline or digitalis for treatment of any other condition
3. Had been enrolled in the trial for an earlier episode of pneumonia
4. Was admitted in a hospital in the previous month
5. History of hypersensitivity or intolerance to amoxicillin or co-trimoxazole

6. History of receiving any antibiotic within last 48 hours, this was be confirmed from health cards or village health workers
7. A history of three or more episodes of wheeze, acute bronchial asthma
8. Evidence of underlying haematologic, renal, hepatic or cardiovascular disease
9. Chronic steroid use or concomitant treatment with theophylline or digitalis glycosides
10. Living outside the study area

Date of first enrolment
05/03/2004

Date of final enrolment
02/06/2006

Locations

Countries of recruitment
United Kingdom

England

Gambia

Study participating centre
Health Protection Agency Centre for Infections
London
United Kingdom
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Sponsor information

Organisation
Medical Research Council Laboratories (Gambia)

ROR
https://ror.org/025wfj672

Funder(s)

Funder type
Research council

Funder Name

Medical Research Council Laboratories (Gambia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration