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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Syed Zaman

#### Contact details

Health Protection Agency Centre for Infections 61 Colindale Avenue London United Kingdom NW9 5EQ

# 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

ОΓ

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 NW9 5EQ

# Sponsor information

## Organisation

Medical Research Council Laboratories (Gambia)

#### **ROR**

https://ror.org/025wfj672

# Funder(s)

# Funder type

Research council

#### **Funder Name**

# **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?

Participant information sheet
Participant information sheet
11/11/2025 No Yes