

Multicentre prospective randomised clinical trial to compare the safety and efficacy of outpatient treatment with oral amoxicillin with that of injectable ampicillin in children aged 3 to 59 months: APPIS II Randomised Controlled Trial (RCT), Pakistan

Submission date 31/03/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 31/03/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/01/2008	Condition category Respiratory	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00227331

Protocol serial number

RPC116

Study information

Scientific Title**Acronym**

APPIS II

Study objectives

The proportion of children aged 3 to 59 months with World Health Organization (WHO) defined severe pneumonia who fail treatment in the oral amoxicillin group will not be greater than the proportion of those who fail in the parenteral ampicillin group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from:

1. Local ethics board on the 2nd December 2004
2. WHO Ethics Research Committee (ERC) on the 23rd March 2005

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

World Health Organization (WHO) defined severe pneumonia

Interventions

1. Parenteral Ampicillin for 2 days then sent home on oral amoxicillin for 3 days
2. Oral Amoxicillin for 5 days

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Amoxicillin, ampicillin

Primary outcome(s)

1. Clinical deterioration occurring any time after enrolment
2. Inability to take oral medication due to persisting vomiting as assessed by study physician
3. Change or addition of antibiotics

Key secondary outcome(s)

1. Treatment failure between day 6 and 14
2. Clinical deterioration (development of danger signs) between day 6 and 14
3. Development of lower chest indrawing or fast breathing, which is non responsive to three trials of nebulisation with bronchodilator between day 6 and 14

Completion date

31/08/2008

Eligibility**Key inclusion criteria**

1. Children aged 3 to 59 months with severe pneumonia. Severe pneumonia is defined as Lower Chest Indrawing (LCI) in children with cough and/or difficult breathing, who are able to drink and do not have central cyanosis, regardless of the respiratory rate
2. Known Human Immunodeficiency Virus (HIV) infected patients in clinical category N or A (Centers for Disease Control [CDC]) will be included
3. Informed consent by a legal guardian

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 Months

Upper age limit

59 Months

Sex

All

Key exclusion criteria

Children with any of the following conditions will be excluded:

1. Very severe pneumonia/disease
2. Known prior episodes of asthma or three or more prior episodes of wheezing
3. LCI that resolves after three doses of bronchodilator therapy
4. Severe malnutrition (visible severe wasting or oedema)
5. Known anaphylactic reaction to penicillin or amoxicillin
6. Hospitalisation in the last two weeks

7. Other diseases requiring antibiotic therapy at presentation, such as meningitis, dysentery, osteomyelitis, septic arthritis, evident tuberculosis etc.
8. Persistent vomiting
9. Previous inclusion in the study
10. Living outside a pre-defined area
11. Parental or caretaker refusal to participate in the study

Date of first enrolment

24/02/2005

Date of final enrolment

31/08/2008

Locations

Countries of recruitment

Pakistan

Switzerland

Study participating centre**World Health Organization**

Geneva-27

Switzerland

CH 1211

Sponsor information

Organisation

The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO)
(Switzerland)

ROR

<https://ror.org/01f80g185>

Funder(s)

Funder type

Research organisation

Funder Name

The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO)
(Switzerland)

Funder Name

US Agency for International Development (USAID) (USA)

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	05/01/2008		Yes	No