

# 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

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

**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**  
NCT00227331

**Secondary identifying numbers**  
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

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

### **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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

24/02/2005

**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

**Age group**

Child

**Lower age limit**

3 Months

**Upper age limit**

59 Months

**Sex**

Both

**Target number of participants**

2100

**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)

**Sponsor details**

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Geneva-27  
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qazis@who.int

**Sponsor type**

Research organisation

**Website**

<http://www.who.int>

**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****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?
<a href="#">Results article</a>	Results	05/01/2008		Yes	No