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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

Registration date
31/03/2006

Overall study status
Completed

Last Edited
15/01/2008

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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
20 Avenue Appia
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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?
Results article	Results	05/01/2008		Yes	No