

# Treatment of community acquired alveolar pneumonia in 6-59 month old children: comparing amoxicillin (80 mg/kg) for 10 days with short course of amoxicillin (80 mg/kg) for 3 days

<b>Submission date</b> 14/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/01/2021	<b>Condition category</b> Respiratory	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

001

# Study information

## Scientific Title

Treatment of community acquired alveolar pneumonia in 6-59 month old children: comparing amoxicillin (80 mg/kg) for 10 days with short course of amoxicillin (80 mg/kg) for 3 days

## Acronym

STOP-CAP

## Study objectives

In children aged 6-59 months with community acquired non-complicated alveolar pneumonia, no significant differences in chance for clinical cure will be found between patients treated for 10 days and patients treated for 3 days with amoxicillin 80 mg/kg/day.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## 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

Community acquired alveolar pneumonia.

## Interventions

Randomised controlled trial comparing amoxicillin (80 mg/kg) for 10 days with a short course of amoxicillin (80 mg/kg) for 3 days.

## Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Amoxicillin

**Primary outcome measure**

The primary outcome is treatment failure defined as:

1. Any patient who will need the study drug replaced
2. Admission to the pediatric wards due to deterioration in medical condition, both after the first 24 hours following the initiation of treatment

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/08/2005

**Completion date**

31/07/2008

**Eligibility****Key inclusion criteria**

Participation in the study will be all infants and young children who meet the following criteria:

1. Children aged 6-59 months who are residents of the Negev region of southern Israel attending the Soroka emergency room (ER)
2. Provision of informed consent required for follow-up visits (visits 2 and 3)
3. Body temperature measured as 38 °C or higher
4. White blood cells count (WBC): 15,000 cells/ml or higher
5. Chest X-ray with alveolar pneumonia as defined by World Health Organisation (WHO)

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

6 Months

**Upper age limit**

59 Months

**Sex**

Both

**Target number of participants**

300

## **Key exclusion criteria**

1. Patients received any systemic antimicrobial therapy 2 weeks or less before enrolment
2. Patient candidate for parenteral treatment:
  - a. Patients with sepsis (pneumonia with impaired perfusion, low blood pressure, oliguria, lactic acidosis, impaired consciousness)
  - b. Pleural effusion in X-ray
  - c. Recurrent vomiting per history or following treatment trial in the ER
3. O2 saturation <94%
4. Patients with impaired immune system
5. Patients with two or more episodes of pneumonia in the 12 months prior to current illness
6. Patients with chronic diseases (patients with asthma are included in this study)
7. Patients with other infection sites such as clinical dysentery, urinary tract infection, acute otitis media (proven by tympanocentesis), or suspecting meningitis
8. Patients allergic to penicillin

## **Date of first enrolment**

01/08/2005

## **Date of final enrolment**

31/07/2008

## **Locations**

### **Countries of recruitment**

Israel

### **Study participating centre**

**Soroka University Medical Center**

Beer Sheva

Israel

84101

## **Sponsor information**

### **Organisation**

Soroka University Medical Center

### **Sponsor details**

Pediatric Infectious Disease Unit

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**Sponsor type**

University/education

**ROR**

<https://ror.org/003sphj24>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Pediatric Infectious Disease Unit, Soroka University Medical Center.

## 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	01/02/2014	12/01/2021	Yes	No