

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

Submission date 14/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/12/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/01/2021	Condition category Respiratory	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Months

Upper age limit

59 Months

Sex

All

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

ROR

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

Funder(s)

Funder type

University/education

Funder Name

Pediatric Infectious Disease Unit, Soroka University Medical Center.

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