ISRCTN59218653 https://doi.org/10.1186/ISRCTN59218653

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	Recruitment status	[_] Prospectively registered
14/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/01/2021	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Ron Dagan

Contact details
Soroka University Medical Center
Beer Sheva
Israel
84101
+972 8 6400547
rdagan@bgu.ac.il

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
Beer Sheva
Israel
84101
+972 8 6400547
dudi@bgu.ac.il

Sponsor type
University/education

ROR
https://ror.org/003sphj24

Funder(s)

Funder type
University/education

Funder Name
Pediatric Indectious 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?
Results article	results	01/02/2014	12/01/2021	Yes	No