

Dose and duration of antibiotic treatment in young children with community-acquired pneumonia

Submission date 14/12/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 15/12/2015	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/01/2024	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Pneumonia (an infection of the lungs) is one of most common infections in young children worldwide. Because there are no good tests to clearly identify whether pneumonia is caused by bacteria in children, the decision to prescribe antibiotics has to be made based on clinical assessment. Therefore antibiotics are very commonly prescribed to children for possible pneumonia. We know that treatment with antibiotics can lead to changes in the bacteria carried by the person taking them, making the bacteria become more resistant to the effect of the antibiotics. These resistant bacteria can subsequently cause an infection in the treated children or spread to other persons in close contact. Infections caused by resistant bacteria are more difficult to treat. The amount of antibiotic (dose) and the number of days of treatment (duration) is likely to have an effect on the development of resistant bacteria in individual patients. Currently, we do not know which antibiotic treatment duration and dose are best for treating childhood pneumonia. Also the relationship between dose, duration and the development of resistant bacteria in the nose and gut (two preferred places where bacteria live) is not understood. This study will look at whether lower doses and shorter duration of antibiotic treatment with amoxicillin, the antibiotic most commonly used for pneumonia in children, are as good at treating pneumonia as higher doses and longer duration of treatment. The aim of the study is to investigate whether 3 days of treatment is as good as 7 days of treatment, and whether a low dose is as good as a high dose for treating pneumonia, and whether these different doses and durations affect the appearance of resistant bacteria. The lower dose and shorter treatment could reduce side effects and cause less resistance. The results of the study could inform how children in the UK and also in other countries should best be treated for pneumonia.

Who can participate?

Parents or carers of children aged greater than 6 months and weighing 6-24 kg are asked to join the study if the child has pneumonia and will be treated at home, as long as there are no signs of very severe pneumonia or other complications. Children seen in the emergency department who

can go home can join the study immediately. Children in hospital often need a short period of intravenous treatment or observation; their carers would be invited to join the study after up to 48 hours of inpatient therapy.

What does the study involve?

Participating children are randomly allocated to be treated with either high or low dose amoxicillin for either 3 or 7 days. In order to treat the groups of children in the same way, neither the doctors nor the families know whether their child is receiving high or low dose amoxicillin. Similarly, while children receiving 7 days have amoxicillin every day, those receiving 3 days have 3 days of amoxicillin followed by 4 days of placebo (medicine with no active ingredients). We compare how frequently children have to be treated again with antibiotics in the different groups. To look at the development of resistant bacteria, nose swabs are collected before starting treatment and up to twice during and after treatment, to find out whether shorter treatments and/or those using a specific dose lead to less resistant bacteria in the nose at the end of treatment.

What are the possible benefits and risks of participating?

The potential benefits of participating are:

1. Dosing of medication is more accurate because it is based on the child's weight.
2. Participants are contacted by the study nurse weekly during the study i.e. participants have more follow-up than normal for a child with pneumonia. Participants are also given a phone number for the study team in case of questions or concerns.
3. The improved understanding of the impact of amoxicillin duration and dose on the development of antibiotic resistance, together with evidence of the effectiveness of different courses, will enable the most appropriate treatment to be identified.

The potential drawbacks of participating are:

1. Amoxicillin given for 3 days may not be as good at treating pneumonia as treatment for 7 days. We think this is unlikely and shorter treatment has been shown to be safe in adults.
2. Participants need to come to the hospital for two extra visits with the study nurse at the end of weeks 1 and 4.

Where is the study run from?

St George's Hospital (UK)

When is the study starting and how long is it expected to run for?

May 2015 to July 2019

Who is funding the study?

National Institute for Health Research Health Technology Assessment Programme (UK)

Who is the main contact?

Sam Barratt

Mrcctu.capit@ucl.ac.uk

Study website

<https://www.capitstudy.org.uk/>

Contact information

Type(s)

Public

Contact name

Mr Sam Barratt

Contact details

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Additional identifiers**EudraCT/CTIS number**

2016-000809-36

IRAS number**ClinicalTrials.gov number****Secondary identifying numbers**

HTA 13/88/11

Study information**Scientific Title**

Efficacy, safety and impact on antimicrobial resistance of duration and dose of amoxicillin treatment for young children with community-acquired pneumonia (CAP): a randomised controlled trial

Acronym

CAP-IT

Study objectives

Current hypothesis as of 21/02/2017:

1. Lower dose (35-50 mg/kg per day given in two divided doses) oral amoxicillin treatment is non-inferior to higher dose (70-90 mg/kg per day in two divided doses) amoxicillin treatment for uncomplicated childhood community-acquired pneumonia (CAP) in terms of resolution /prevention of relapse of lower respiratory illness requiring retreatment with antibiotics.
2. Shorter duration (3 days) amoxicillin treatment is non-inferior to longer duration (7 days) amoxicillin treatment for uncomplicated childhood CAP.

Previous hypothesis:

1. Lower dose (35-50 mg/kg per day given in two divided doses) oral amoxicillin treatment is non-inferior to higher dose (70-120 mg/kg per day in two divided doses) amoxicillin treatment for uncomplicated childhood community-acquired pneumonia (CAP) in terms of resolution

/prevention of relapse of lower respiratory illness requiring retreatment with antibiotics.
2. Shorter duration (3 days) amoxicillin treatment is non-inferior to longer duration (7 days) amoxicillin treatment for uncomplicated childhood CAP.

More details can be found here: <https://www.journalslibrary.nihr.ac.uk/programmes/hta/138811/#/>

Ethics approval required

Old ethics approval format

Ethics approval(s)

London - West London & GTAC Research Ethics Committee, 30/06/2016

Study design

Multi-centre UK-based randomised double-blind placebo-controlled 2x2 factorial non-inferiority trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Community-acquired pneumonia

Interventions

Current interventions as of 21/02/2017:

Children will be enrolled from Paediatric Emergency Departments (PEDs) at university centres (main sites) and from the wards of the main sites and their affiliated secondary care hospitals (satellite sites).

Participants will be randomised to:

Randomisation 1: Lower dose (35-50 mg/kg per day given in two divided doses) oral amoxicillin treatment versus higher dose (70-90 mg/kg per day in two divided doses) oral amoxicillin treatment. Dose volumes will be identical in the lower and higher dose groups.

Randomisation 2: Three days of oral amoxicillin followed either by placebo for 4 days (3 days active treatment) or by a further 4 days of amoxicillin (7 days active treatment).

This will result in four treatment groups:

1. Longer/lower dose: 7 days at 35-50 mg/kg/day

2. Shorter/lower dose: 3 days at 35-50 mg/kg/day
3. Longer/higher dose: 7 days at 70-90 mg/kg/day
4. Shorter/higher dose: 3 days at 70-90 mg/kg/day

Previous interventions:

Children will be enrolled from Paediatric Emergency Departments (PEDs) at university centres (main sites) and from the wards of the main sites and their affiliated secondary care hospitals (satellite sites).

Participants will be randomised to:

Randomisation 1: Lower dose (35-50 mg/kg per day given in two divided doses) oral amoxicillin treatment versus higher dose (70-120 mg/kg per day in two divided doses) oral amoxicillin treatment. Dose volumes will be identical in the lower and higher dose groups.

Randomisation 2: Three days of oral amoxicillin followed either by placebo for 4 days (3 days active treatment) or by a further 4 days of amoxicillin (7 days active treatment).

This will result in four treatment groups:

1. Longer/lower dose: 7 days at 35-50 mg/kg/day
2. Shorter/lower dose: 3 days at 35-50 mg/kg/day
3. Longer/higher dose: 7 days at 70-120 mg/kg/day
4. Shorter/higher dose: 3 days at 70-120 mg/kg/day

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Amoxicillin

Primary outcome measure

Current primary outcome measure as of 05/07/2018:

The primary outcome is defined as any systemic antibacterial treatment in addition to the allocated trial medication as an inpatient or outpatient up to and including week 4 final follow-up. This includes re-treatment, increase in amoxicillin dose, extension of treatment and treatment with additional agents.

Previous primary outcome measure:

Any antibiotic treatment prescribed in addition to the allocated trial medication as an in- or out-patient up to and at final follow-up. This includes retreatment, extension of treatment and treatment with additional agents. Measured at weeks 1, 2, 3 and 4.

Secondary outcome measures

Current secondary outcome measures as of 05/07/2018:

1. Morbidity assessed using:

1.1. Specified clinical adverse events, including thrush, skin rashes and diarrhoea assessed at weeks 1, 2, 3 and 4 (final visit)

1.2. Severity and duration of parent/guardian-reported CAP symptoms assessed using a validated symptom diary at days 1-7 and weeks 2, 3 and 4

1.3. Number of days off work for parents/guardians and number of days away from out-of-home

- child care (where relevant), assessed using the parent diary on day 7 and day 14
2. Phenotypic resistance to penicillin at week 4 measured through microbiological analysis of *S. pneumoniae* isolates colonising the nasopharynx from nasopharyngeal samples at the baseline, final visit and any unscheduled visits
 3. Adherence to trial drug assessed on days 1-7 via the parent diary and at follow up visit at week 1 or 4
 4. Antibiotic use, collected at weeks 1, 2, 3 and 4, assessed using:
 - 4.1. Cumulative number of additional courses of antibiotics
 - 4.2. Total number of days of re-treatment with antibiotics
 5. Health-economic outcomes assessed at day 7 and day 14 through the parent diary and at days 7, 15, 22 and 29 on follow up calls/visits:
 - 5.1. Quality of life (using EQ-5D adapted for use in the paediatric population) assessed at weeks 1, 2, 3 and 4 (final visit)
 - 5.2. Cost-causing events and associated resource use, including costs based on patient admission and discharge dates, treatment costs and costs associated with treatment failure such as re-admissions and re-treatments. Assessed through completion of a table of the number of times contacted and number of times visited for A&E/walk-in centres, out of hours service, paediatrician, GP practice, pharmacist, NHS direct/NHS 111

Previous secondary outcome measures:

1. Adverse events, assessed at weeks 1, 2, 3 and 4 (final visit)
2. Severity and duration of parent-reported CAP symptoms, assessed using a validated symptom diary at days 1-7 and weeks 2, 3 and 4
3. Health economics measured using EQ-5D adapted for use in the paediatric population at weeks 1, 2, 3 and 4 (final visit)
4. Details of additional courses of antibiotics and total number of days of re-treatment with antibiotics, collected at weeks 1, 2, 3 and 4
5. Adherence, assessed on days 1-7 via the parent diary and at follow up visit at week 1 or 4
6. Penicillin resistance, assessed using samples taken at baseline, week 1 (during the pilot phase) and week 4

Overall study start date

01/05/2015

Completion date

31/07/2019

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 31/05/2019:

PED:

1. Age greater than 6 months and weighing 6 - 24kg
2. Clinical diagnosis of CAP at presentation to PED as defined by all of the following:
 - 2.1 Presence of cough (reported by parents/guardians within 96 hours prior to presentation)AND
 - 2.2 Temperature $\geq 38^{\circ}\text{C}$ measured by any method OR likely fever within 48 hours prior to presentation AND
 - 2.3 Signs of laboured/difficult breathing or focal chest signs at presentation in the PED (i.e. one or more of the following):
 - 2.3.1 Nasal flaring

- 2.3.2 Chest retractions
- 2.3.3 Abdominal breathing
- 2.3.4 Focal dullness to percussion
- 2.3.5 Focal reduced breath sounds
- 2.3.6 Crackles with asymmetry
- 2.3.7 Lobar pneumonia on chest X-ray (if obtained)
- 3. Prior antibiotic treatment:
 - 3.1 Not on systemic antibiotic treatment at presentation OR
 - 3.2 Treated in the community as an outpatient with uninterrupted oral beta-lactam antibiotics for ≤ 48 hours
- 4. Decision to treat with oral amoxicillin for CAP on discharge from hospital
- 5. Parent/guardian willing to accept all possible randomised allocations
- 6. Available for follow up for the entire study period, parent/guardian willing to be contacted by telephone at day 4, weeks 1, 2 and 3, and attend a face-to-face follow up visit at 4 weeks after randomisation, unless discussed with MRC CTU
- 7. Informed consent form for trial participation signed by parent/guardian.

WARD:

- 1. Age greater than 6 months and weighing 6 - 24kg.
- 2. Clinical diagnosis of CAP at presentation to hospital as defined by all of the following:
 - 2.1 Presence of cough (reported by parents/guardians within 96 hours prior to presentation)
- AND;
- 2.2 Temperature $\geq 38^{\circ}\text{C}$ measured by any method OR likely fever within 48 hours prior to presentation AND;
- 2.3 Signs of laboured/difficult breathing or focal chest signs (i.e. one or more of the following):
 - 2.3.1 Nasal flaring
 - 2.3.2 Chest retractions
 - 2.3.3 Abdominal breathing
 - 2.3.4 Focal dullness to percussion
 - 2.3.5 Focal reduced breath sounds
 - 2.3.6 Crackles with asymmetry
 - 2.3.7 Lobar pneumonia on chest X-ray (if obtained)
- 3. Prior antibiotic treatment including doses administered in hospital (see Figure 2):
 - 3.1 Treated in-hospital only with any oral or intravenous beta-lactam for ≤ 48 hours after admission
 - 3.2 Treated initially in the community and subsequently in hospital with any oral or intravenous beta-lactam, without interruption, for ≤ 48 hours in total
- 4. Decision to further treat with oral amoxicillin for CAP on discharge from hospital
- 5. Child is considered fit for discharge at time of randomisation
- 6. Available for follow up for the entire study period, parent/guardian willing to be contacted by telephone at weeks 1, 2 and 3 and attend face-to-face follow up visit at 4 weeks after randomisation, unless discussed with MRC CTU
- 7. Parent/guardian willing to accept all possible randomised allocations
- 8. Informed consent for trial participation signed by a parent/guardian

Previous participant inclusion criteria from 05/07/2018 to 31/05/2019:

PED group:

- 1. Age greater than 6 months and weighing 6-24 kg
- 2. Clinical diagnosis of CAP at presentation to PED as defined by all of the following:
 - 2.1. Presence of cough (reported by parents/guardians in last 96 hours) AND
 - 2.2. Temperature $\geq 38^{\circ}\text{C}$ measured by any method or likely fever in last 48 hours AND
 - 2.3. Signs of laboured/difficult breathing or focal chest signs at presentation in the PED (i.e. one

or more of the following):

- 2.3.1. Nasal flaring
- 2.3.2. Chest retractions
- 2.3.3. Abdominal breathing
- 2.3.4. Focal dullness to percussion
- 2.3.5. Focal reduced breath sounds
- 2.3.6. Focal crackles
3. Prior antibiotic treatment:
 - 3.1. Not on systemic antibiotic treatment at presentation OR
 - 3.2. Treated in the community as an outpatient with uninterrupted oral beta-lactam antibiotics for ≤ 48 hours
4. Decision to treat with oral amoxicillin for CAP on discharge from hospital
5. Parent/guardian willing to accept all possible randomised allocations
6. Available for follow up for the entire study period, parent/guardian willing to be contacted by telephone at day 4, weeks 1, 2 and 3, and attend a face-to-face follow up visit at 4 weeks after randomisation, unless discussed with MRC CTU
7. Informed consent form for trial participation signed by parent/guardian.

WARD group:

1. Age greater than 6 months and weighing 6-24 kg
2. Clinical diagnosis of CAP at presentation to PED as defined by all of the following:
 - 2.1. Presence of cough (reported by parents/guardians in last 96 hours) AND
 - 2.2. Temperature $\geq 38^{\circ}\text{C}$ measured by any method or likely fever in last 48 hours AND
 - 2.3. Signs of laboured/difficult breathing or focal chest signs at presentation in the PED (i.e. one or more of the following):
 - 2.3.1. Nasal flaring
 - 2.3.2. Chest retractions
 - 2.3.3. Abdominal breathing
 - 2.3.4. Focal dullness to percussion
 - 2.3.5. Focal reduced breath sounds
 - 2.3.6. Focal crackles
3. Child admitted to a paediatric assessment unit or inpatient ward at a participating hospital
4. Decision to treat with oral or intravenous beta-lactam for ≤ 48 hours after admission
5. Decision to further treat with oral amoxicillin for CAP on discharge from hospital
6. Child is considered fit for discharge at time of randomisation
7. Available for follow up for the entire study period, parent/guardian willing to be contacted by telephone at day 4, weeks 1, 2 and 3, and attend a face-to-face follow up visit at 4 weeks after randomisation, unless discussed with MRC CTU
8. Parent/guardian willing to accept all possible randomised allocations
9. Informed consent for trial participation signed by a parent/guardian

Original participant inclusion criteria:

The inclusion criteria differ between the PED and WARD group patients and these are presented separately for clarity.

PED group:

1. Age from 1 to 5 years (up to their 6th birthday)
2. Clinical diagnosis of CAP as defined by the following (note: all four criteria must be met for the child to be eligible):
 - 2.1. Presence of cough (reported by parents/guardians in last 96 hours)
 - 2.2. Temperature $\geq 38^{\circ}\text{C}$ measured by any method or history of fever in last 24 hours reported by parents/guardians
 - 2.3. Increased age-specific respiratory rate (first or second triage or clinical examination by a

member of clinical staff)

2.4. Signs of laboured/difficult breathing or focal chest signs at presentation in the PED (one or more of the following):

2.4.1. Nasal flaring

2.4.2. Chest retractions

2.4.3. Abdominal breathing

2.4.4. Focal dullness to percussion

2.4.5. Focal reduced breath sounds

2.4.6. Focal crackles

3. Decision to treat with oral amoxicillin for CAP

4. Decision to be discharged from the paediatric emergency department immediately

5. Parent/guardian willing to accept all possible randomised allocations

6. Available for follow up for the entire study period and parent/guardian willing to be contacted by telephone

7. Informed consent form for trial participation signed by parent/guardian.

WARD group:

1. Age from 1 to 5 years (up to their 6th birthday)

2.1. Presence of cough (reported by parents/guardians in last 96 hours)

2.2. Temperature $\geq 38^{\circ}\text{C}$ measured by any method or history of fever in last 24 hours reported by parents/guardians

2.3. Increased age-specific respiratory rate (first or second triage or clinical examination by a member of clinical staff)

2.4. Signs of laboured/difficult breathing or focal chest signs (one or more of the following):

2.4.1. Nasal flaring

2.4.2. Chest retractions

2.4.3. Abdominal breathing

2.4.4. Focal dullness to percussion

2.4.5. Focal reduced breath sounds

2.4.6. Focal crackles

3. Child admitted to a paediatric assessment unit or inpatient ward at a participating hospital (main site or satellite site).

4. Decision to treat with antibiotics during the ≤ 48 hours after admission with oral or intravenous amoxicillin or co-amoxicillin

5. Child planned for discharge on the same day as randomisation

6. Available for follow up for the entire study period and parent/guardian willing to be contacted by telephone

7. Parent/guardian willing to accept all possible randomised allocations

8. Informed consent for trial participation signed by a parent/guardian

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

800

Total final enrolment

824

Key exclusion criteria

Current participant exclusion criteria as of 31/05/2019:

PED:

1. Severe underlying chronic disease with an increased risk of developing complicated CAP including sickle cell anaemia, primary or secondary immunodeficiency, chronic lung disease and cystic fibrosis
2. Documented penicillin allergy
3. Any other known contra-indication to amoxicillin
4. Need for systemic treatment with an antibiotic other than amoxicillin on discharge from hospital
5. Bilateral wheezing without focal chest signs (most likely to represent respiratory tract infection of non-bacterial aetiology)
6. Complicated pneumonia
7. Receipt of initial antibiotic treatment in hospital in PAU or on the ward*
8. Parents/guardians unlikely to reliably complete the diary because of significant language barriers.

WARD:

1. Severe underlying chronic disease with an increased risk of complicated CAP including sickle cell anaemia, primary or secondary immunodeficiency, chronic lung disease and cystic fibrosis
2. Documented penicillin allergy
3. Any other known contra-indication to taking amoxicillin
4. Bilateral wheezing without focal chest signs (most likely to represent respiratory tract infection of non-bacterial aetiology)
5. Complicated pneumonia
6. Receipt of antibiotic other than a beta-lactam during admission
7. If treated in the community prior to admission, receipt of a non-beta-lactam antibiotic in the community at presentation
8. Clinically relevant positive blood culture (i.e. positive blood culture and clinical decision to prolong intravenous treatment for more than 48 hours or inappropriate to switch to amoxicillin therapy)
9. Receipt of >48 hours oral or intravenous antibiotic treatment in total
10. Decision to treat with oral antibiotic other than amoxicillin on discharge from hospital
11. Parents/guardians unlikely to reliably complete the diary because of significant language barriers.

Previous participant exclusion criteria from 05/07/2018 to 31/05/2019:

PED group:

1. Severe underlying chronic disease including sickle cell anaemia, primary or secondary immunodeficiency, chronic lung disease and cystic fibrosis
2. Documented penicillin allergy
3. Any other known contra-indication to taking amoxicillin
4. Need for system treatment with an antibiotic other than amoxicillin on discharge from hospital
5. Bilateral wheezing without focal chest signs (most likely to represent respiratory tract infection of non-bacterial aetiology)
6. Complicated pneumonia

7. Receipt of initial antibiotic treatment as inpatient in PAU or on the ward
8. Parent/ guardians unlikely to reliably complete the diary because of significant language barriers

WARD group:

1. Severe underlying chronic disease including sickle cell anaemia, primary or secondary immunodeficiency, chronic lung disease and cystic fibrosis
2. Documented penicillin allergy
3. Any other known contra-indication to taking amoxicillin
4. Already on antibiotic treatment at presentation
5. Bilateral wheezing without focal chest signs (most likely to represent respiratory tract infection of non-bacterial aetiology)
6. Complicated pneumonia
7. Receipt of antibiotic other than a beta-lactam during admission
8. Clinically relevant positive blood culture (i.e. positive blood culture and clinical decision to prolong intravenous treatment for more than 48 hours or inappropriate to switch to amoxicillin therapy)
9. Receipt of >48 hours oral or intravenous inpatient antibiotic treatment
10. Decision to treat with oral antibiotic other than amoxicillin on discharge from hospital
11. Parent/ guardians unlikely to reliably complete the diary because of significant language barriers

Original participant exclusion criteria:

The exclusion criteria differ between the PED and WARD group patients and these are presented separately for clarity.

PED group:

1. Severe underlying chronic disease including sickle cell anaemia, primary or secondary immunodeficiency, chronic lung disease and cystic fibrosis
2. Documented penicillin allergy
3. Any other known contra-indication to taking amoxicillin
4. Already on antibiotic treatment at presentation
5. Wheezing (most likely to represent respiratory tract infection of non-bacterial aetiology)
6. Complicated pneumonia
7. Antibiotic exposure within the last month
8. Weight is >24 kg

WARD group:

1. Severe underlying chronic disease including sickle cell anaemia, primary or secondary immunodeficiency, chronic lung disease and cystic fibrosis
2. Documented penicillin allergy
3. Any other known contra-indication to taking amoxicillin
4. Already on antibiotic treatment at presentation
5. Wheezing (most likely to represent respiratory tract infection of non-bacterial aetiology)
6. Complicated pneumonia
7. Antibiotic exposure within the last month
8. Clinically relevant positive blood culture (i.e., positive blood culture and clinical decision to prolong intravenous treatment for more than 48 hours or to switch to antibiotic therapy other than co-amoxicillin/amoxicillin)
9. Persistent or increasing oxygen requirement at ≤ 48 hours of admission compared with on admission
10. Persistent or deteriorating tachypnoea at ≤ 48 hours of admission compared with on admission

11. Receipt of non-amoxicillin-based therapy since admission (either as combination therapy with amoxicillin or as standalone antibiotic therapy)
12. Receipt of >48 hours oral or intravenous inpatient antibiotic treatment
13. Decision to treat with oral antibiotic other than amoxicillin on discharge from hospital
14. Weight is >24 kg

Date of first enrolment

01/02/2017

Date of final enrolment

30/04/2019

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St George's Hospital

United Kingdom

SW17 0QT

Sponsor information

Organisation

University College London (UK)

Sponsor details

Gower Street

London

England

United Kingdom

WC1E 6BT

Sponsor type

University/education

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

To achieve the greatest possible dissemination the results will be communicated using appropriate channels to:

1. Antibiotic prescribers: Open Access publication in high impact peer-review journals likely to be read by healthcare professionals involved in the management of CAP in children in the UK
2. Policymakers/stakeholders: An annual newsletter will be published and relevant findings summarised for key stakeholders such as the Royal Colleges, relevant Commissioners of children's services and participating networks
3. British National Formulary for Children: Members of the CAP-IT study team are lead clinical advisors for the BNFC on anti-infectives
4. Funders: A final report will be prepared for the HTA
5. Public/parents: A project website will be developed and information made available there. In addition, press releases will be generated at key points to make relevant information about CAP-IT available to the general public. Finally, the families of all participants will be informed of the trial results by email or post.

Intention to publish date

01/11/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. David Dunn (d.dunn@ucl.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/05/2019	01/06/2020	Yes	No
Results article		02/11/2021	03/11/2021	Yes	No
Results article		01/11/2021	08/11/2021	Yes	No
Statistical Analysis Plan	version 2.0	02/12/2020	18/01/2024	No	No