

Prevent Pseudomonas Aeruginosa Colonisation

Submission date 12/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/10/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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
2008-001769-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7857

Study information

Scientific Title

Randomised controlled trial to assess the benefits of early use ciprofloxacin versus placebo in children with cystic fibrosis to minimise the risks of chronic infection with pseudomonas aeruginosa

Acronym

PREPAC

Study objectives

Randomised controlled trial to assess the benefits of early use of ciprofloxacin in children with cystic fibrosis to minimise the risks of chronic infection with pseudomonas aeruginosa.

More details can be found here: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=7857>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Southampton and South West Hampshire LREC B, August 2008, ref: 08/H0504/110

Study design

Single-centre randomised interventional treatment 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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions

Study participants randomised to receive active study medication or placebo at times of onset of viral respiratory tract infections:

1. Active arm: ciprofloxacin suspension 30 mg/kg/day for patients aged 2 - 5 years and 40 mg/kg /day (maximum 1,500 mg/24 hours) in those aged 5 - 14 years in a twice daily dose for 14 days
2. Control arm: placebo (ciprofloxacin diluent without added drug) for 14 days

Follow up length: 32 months

Study entry: single randomisation only

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ciprofloxacin

Primary outcome measure

Pseudomonas infection, accrual of all study data at end of 32-month trial period.

Secondary outcome measures

1. Time to first detection of pseudomonas at routine 2-monthly clinic visits using both conventional and molecular biological specimens
2. Number of infective exacerbations needing hospital admission/intravenous treatment
3. Cost-benefit analysis of health care resource utilisation as a result of use of ciprofloxacin
4. Difference in symptom diary recording of lower respiratory symptoms
5. Conventional and molecular microbiological data will also be explored to determine the relationship between specific viral infections and the occurrence of P. aeruginosa at the time of acute viral infection
6. Differences in serum enzyme-linked immunosorbent assay (ELISA) assays for pseudomonas between the beginning and end of the study

Overall study start date

01/12/2009

Completion date

31/12/2012

Eligibility**Key inclusion criteria**

1. Confirmed diagnosis of cystic fibrosis and attending the regional CF service for care exclusively at Southampton or at Southampton and Winchester or Poole General Hospitals
2. Aged 2 - 14 years, either sex
3. Negative ELISA serology for P. aeruginosa at study entry
4. Not chronically infected with pseudomonas aeruginosa

Participant type(s)

Patient

Age group

Child

Lower age limit

2 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

Planned sample size: 45; UK sample size: 45

Key exclusion criteria

1. Positive pseudomonas serology on ELISA testing
 2. Any other evidence suggesting chronic P. aeruginosa infection
 3. Chronic infection with any other gram negative CF pathogen
 4. Past history of allergic reaction or any other significant adverse reaction to previous treatment with oral ciprofloxacin
 5. Ongoing participation any other clinical trial at time of study entry
 6. Parents or guardians unwilling to give informed consent for study inclusion
 7. Patients who have a recognised indication for other antibiotics
 8. Immunosuppressive/immunomodulatory therapy
 9. Significant immunocompromise (e.g., human immunodeficiency virus [HIV] infection)
 10. Advanced malignancy
 11. Burns
 12. Children not likely to survive the time period of the intervention
 13. Patients who have undergone organ transplantation (including bone marrow transplantation)
 14. Patients undergoing plasma exchange or whole blood exchange transfusion
 15. Treatment with an investigational drug or device within the last 30 days prior to enrolment
 16. Immediate families of investigators or site personnel directly affiliated with the study.
- Immediate family is defined as child or sibling, whether biological or legally adopted.

Date of first enrolment

01/12/2009

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Southampton Clinical Trials Unit, MP131

Southampton

United Kingdom

SO16 6YD

Sponsor information

Organisation

Southampton University Hospitals NHS Trust (UK)

Sponsor details

Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor type

Not defined

Website

<http://www.soton.ac.uk/>

ROR

<https://ror.org/0485axj58>

Funder(s)

Funder type

Charity

Funder Name

Sparks (UK)

Alternative Name(s)

Sparks Charity

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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	01/12/2015		Yes	No