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Prevent Pseudomonas Aeruginosa Colonisation

Submission date	Recruitment status	[_] Prospectively registered
12/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/10/2017	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-001769-27

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 years

Upper age limit
14 years

Sex
All

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
United Kingdom

England

Study participating centre
University of Southampton Clinical Trials Unit, MP131
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (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

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