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Respiratory infections with Pseudomonas aeruginosa in children with Cystic Fibrosis; early surveillance and prevention

Submission date	Recruitment status
12/09/2005	No longer recruiting
Registration date	**Overall study status**
12/09/2005	Completed
Last Edited	**Condition category**
20/09/2010	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR64

Study information

Scientific Title

Acronym
POPeye-study

Study objectives
Our hypothesis is that the initial infection with P. aeruginosa occurs at earlier age than previously reported and that prophylactic treatment of P. aeruginosa-negative CF-patients will either prevent or delay the first acquisition of P.aeruginosa or eradicate the organism before the onset of persistent colonization and accompanying pulmonary inflammatory response.

Please note that as of 12/09/2008, the sources of funding field was updated. The anticipated end date of this trial was also updated. The previous anticipated end date was 01/11/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre, randomised, double blinded, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Pulmonary P. aeruginosa infection, cystic fibrosis

Interventions
Ciprofloxacin 10 mg/kg orally (po) or matching placebo twice daily (bid) and colistin 1 MIU inhalation or matching placebo bid. Three-monthly courses of three weeks, total study duration 3 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Early P. aeruginosa colonisation as confirmed by:
1. Persistence of P. aeruginosa in sputum or oropharygeal swab culture in two consecutive samples, taken greater than 3 days apart
2. P. aeruginosa in one oropharyngeal swab or sputum culture with pulmonary exacerbation

Secondary outcome measures
Microbiological:
1. Age at first positive culture
2. Time to P. aeruginosa colonisation
3. Respiratory pathogens in culture
4. Resistance pattern of respiratory pathogens

Serological:
5. Seroconversion for anti-pseudomonal antibodies

Clinical:
6. Adverse events
7. Clinical parameters (lung function, body weight and chest radiograph scores, inflammation parameters)
8. Number of pulmonal exacerbations
9. Antimicrobial agent use

Overall study start date
01/07/2005

Completion date
01/03/2009

Eligibility

Key inclusion criteria
1. CF diagnosis as confirmed by sweat chloride test and/or genotyping
2. Aged less than 18 years old
3. No evidence of P. aeruginosa in cultures taken in period 2004 - 2005
4. Antibody titer less than 1:1250 for three antigens of P. aeruginosa
5. No regular treatment against P. aeruginosa
6. Informed consent

Participant type(s)
Patient

Age group
Child

Upper age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Aged greater than 18 years
2. P. aeruginosa in cultures after 2003
3. Participating in another trial

Date of first enrolment
01/07/2005

Date of final enrolment
01/03/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Wilhelmina Kinderziekenhuis
Utrecht
Netherlands
3508 AB

Sponsor information

Organisation
University Medical Center Utrecht (UMCU) (The Netherlands)

Sponsor details
Heidelberglaan 100
Utrecht
Netherlands
3584 CX

Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Research organisation

Funder Name
Added 12/09/2008:

Funder Name
Initial funding was from the investigator for one year (Netherlands)

Funder Name
Dutch Cystic Fibrosis Foundation (Netherlands)

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	01/10/2010		Yes	No