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

Gepubliceerd: 12-07-2005 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25471

Bron
NTR

Verkorte titel
POPeye-study

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Early P. aeruginosa colonization as confirmed by
-persistence of P. aeruginosa in sputum or oropharygeal swab culture in two consecutive samples, taken > 3 days apart;
-P. aeruginosa in one oropharyngeal swab or sputum culture with pulmonary exacerbation.

Toelichting onderzoek

Achtergrond van het onderzoek

Cystic fibrosis (CF) is an autosomal recessive disease characterized by chronic obstructive pulmonary disease with recurrent respiratory tract infections. Chronic colonization with P. aeruginosa is a major cause of progressive loss of lung function, morbidity and mortality. Initial acquisition and transient colonization is transformed into an irreversible chronic colonization with antibiotic-resistent bacteria embedded in a biofilm in about 12 months. The prevalence of P. aeruginosa colonization increases from 20% of patients by age 1 until 80-85% by age 20. Early antimicrobial treatment of initial infection probably delays chronic colonization. However, diagnosis of P.aeruginosa infection with traditionally performed oropharyngeal cultures is insensitive and colonization of P.aeruginosa often reappears after interruption of antimicrobial treatment.

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.

Serological evaluation for anti-pseudomonal antibodies and culture of sputum will be performed in addition to the traditional oropharyngeal cultures to improve early P.aeruginosa detection. A 3-years randomized, placebo-controlled trial will be performed in P. aeruginosa-negative CF patients to evaluate the effect of three-monthly courses of inhaled colistin (106 IU b.i.d) and oral ciprofloxacin (20 mg/kg/day) on the acquisition of P. aeruginosa.

The present project aims to early identify P.aeruginosa infection in the course of CF and to find support for the use of prophylactic antimicrobial treatment to prevent or delay the early colonization of P. aeruginosa to preserve lung function.

Study questions:

1. Can the sensitivity of the surveillance of initial P. aeruginosa infection in children with CF be improved by measurement of anti-Pseudomonal antibodies?

2. Can the initial P. aeruginosa infection or early colonization be prevented or delayed by the prophylactic treatment of 3-monthly courses of inhaled colistin and oral ciprofloxacin?

3. What are the determinants for P.aeruginosa acquisition in children with CF?

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

Ciprofloxacin 10 mg/kg po. or matching placebo bid & colistin 1 MIU inhalation or matching placebo bid;
3-monthly courses of 3 weeks, total study duration 3 years.

Contactpersonen

Publiek

University Medical Center Utrecht (UMCU), Wilhelmina Children's Hospital (WKZ), KH.01.419.0
P.O. Box 85090
Gerdien A. Tramper-Stranders
Utrecht 3508 AB
The Netherlands
+31 (0)30 2504000

Wetenschappelijk

University Medical Center Utrecht (UMCU), Wilhelmina Children's Hospital (WKZ), KH.01.419.0
P.O. Box 85090
Gerdien A. Tramper-Stranders
Utrecht 3508 AB
The Netherlands
+31 (0)30 2504000

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. CF diagnosis as confirmed by sweat chloride test and/or genotyping;

2. Age< 18 y;

3. No evidence of P. aeruginosa in cultures taken in period 2004-2005;

4. Antibody titer < 1: 1250 for three antigens of P. aeruginosa;

5. No regular treatment against P. aeruginosa;

6. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age > 18 years;

2. P. aeruginosa in cultures after 2003;

3. Participating in another trial.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2005
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-07-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL37
NTR-old	NTR64
Ander register	: N/A
ISRCTN	ISRCTN11604593

Resultaten

Samenvatting resultaten
A controlled trial of cycled antibiotic prophylaxis to prevent initial Pseudomonas aeruginosa infection in children with cystic fibrosis.
G.A. Tramper-Stranders, T.F.W. Wolfs, S. van Haren Noman, W.M.C. van Aalderen, A.F. Nagelkerke, M. Nuijsink, J.L.L. Kimpen, C.K. van der Ent.
Thorax 2010 Oct;65:915-20