Cystic fibrosis; a hereditary inflammatory process.

Gepubliceerd: 26-07-2005 Laatst bijgewerkt: 18-08-2022

N/A

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

Samenvatting

ID

NL-OMON27281

Bron
NTR

Verkorte titel
N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

PULMONARY:
1. FEV1, FVC, RV%TLC after 3 years;
2. Rint measurements.

Toelichting onderzoek

Achtergrond van het onderzoek

One out of 3600 new-born children in the Netherlands has Cystic Fibrosis (CF). It is an autosomal recessive disease and about 70% of the Dutch CF-patients are homozygous for the

ΔF508 mutation. Although the genetic mutation is identical in this group of patients, the pulmonary disease is very diverse. Causative factors are environmental and also co-genetic ones. Morbidity is caused by chronic inflammation and infection of the lungs, which leads to irreversible lung damage. Neutrophils play a key role in the inflammatory cascade. It is assumed that parts of the acute inflammatory response of the neutrophil (chemotaxis/IL8 „± adhesion/selectines„± activation/TNFa „± production of e.g. superoxides or myeloperoxidase „±tissue destruction) play an important role in the inflammatory process in CF. There is a higher concentration of mediators (IL-8, sICAM1, sE-Selectin, TNFa) in patients with CF than in other patients with airway infections.
The CFTR protein acts not only as a Cl channel but also as a Na/H antiport and influences the intracellular pH. This might affect the functional activity of the neutrophil. Recently, new activation markers (MoPhabs A17 and A27) located on leukocytes were described that may be an early sign of pulmonary inflammation.
To be able to predict and intervene in the inflammatory process would improve the prognosis especially in young children before the process of irreversible lung damage.

The use of new and powerful inhaled corticosteroid medication enables us to give anti-inflammatory therapy to young children without the systemic side-effects of orally administered steroids.

Doel van het onderzoek

N/A

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Inhaled HFA-Beclomethasone Diproprionate (Qvar®) 200 mcg twice daily by aerochamber or a placebo (also inhaled by aerochamber).

Contactpersonen

Publiek

University Medical Center Utrecht (UMCU), locatie AZU, CF-Centrum,
P.O.Box 85500
S.W.J. Terheggen-Lagro
Heidelberglaan 100
Utrecht 3508 GA
The Netherlands

+31 (0)30 2504000

Wetenschappelijk

University Medical Center Utrecht (UMCU), locatie AZU, CF-Centrum,
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S.W.J. Terheggen-Lagro
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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. CF-patients 2-10 years old;

3. Informed consent;

4. Capable of using inhaled
corticosteroids by aerochamber;

5. Compliant to regular therapy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. CF-patients < 2 years;

2. CF-patients > 10 years;

3. Use of anti-inflammatory therapy in a period of 2 months before inclusion (orally administered steroids, inhaled corticosteroïds and non-steroïd anti-inflammatory drugs, NSAID’s);

4. Disease, other than CF, that affects growth;

5. Participation in another study.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2002
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	26-07-2005
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	NL61
NTR-old	NTR91
Ander register	: N/A
ISRCTN	ISRCTN03484127

Resultaten

Samenvatting resultaten
N/A