ISRCTN03484127 https://doi.org/10.1186/ISRCTN03484127

# Cystic fibrosis: a hereditary inflammatory process

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 12/09/2005 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 12/09/2005 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 17/09/2008 | Nutritional, Metabolic, Endocrine | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
NTR91

## Study information

**Scientific Title**

## Study objectives
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 delta-F508 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.

## Ethics approval required
Old ethics approval format

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

## Study design
Randomised, double blind, placebo controlled, parallel group trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Cystic fibrosis

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

## Intervention Type
Drug

## Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Inhaled HFA-Beclomethasone Diproprionate

### Primary outcome(s)
Pulmonary
1. Forced expiratory volume in one second (FEV1), forced vital capacity (FVC), residual volume (RV)/total lung capacity (TLC) % after 3 years
2. Rint measurements

### Key secondary outcome(s))
Immunological:
1. Neutrophil markers: MoPhabs A17 and A27, CD11b, CD11a
2. Interleukin-8 (IL-8), soluble intercellular adhesion molecule 1 (sICAM1), sE-Selectin, tumour necrotising factor alpha (TNFa)
3. End tidal carbon monoxide in exhaled breath

Microbiological:
1. Respiratory pathogens in culture

Serological:
1. Seroconversion to anti-pseudomonal antibodies

Clinical:
1. Adverse events
2. Clinical parameters (body weight, height, fat free mass)
3. Number of pulmonary exacerbations
4. Antimicrobial agent use
5. Quality of life questionnaire scores

Radiological:
1. Chest radiograph scored by CF chest radiograph scoring systems

### Completion date
01/12/2005

## Eligibility

### Key inclusion criteria
For 3-years randomised controlled trial:
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

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
2 years

### Upper age limit
10 years

### Sex
All

### Key exclusion criteria
For 3-years randomised controlled trial:
1. CF-patients less than 2 years
2. CF-patients greater than 10 years
3. Use of anti-inflammatory therapy in a period of 2 months before inclusion (orally administered steroids, inhaled corticosteroids and non-steroid anti-inflammatory drugs, non-steroidal anti-inflammatory drugs [NSAIDs])
4. Disease, other than CF, that affects growth
5. Participation in another study

### Date of first enrolment
01/01/2002

### Date of final enrolment
01/12/2005

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**Universitair Medisch Centrum, locatie AZU**
Utrecht
Netherlands
3508 GA

## Sponsor information

### Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

### ROR

https://ror.org/04pp8hn57

# Funder(s)

**Funder type**
Government

**Funder Name**
The Netherlands Organization for Scientific Research (NWO) (The Netherlands)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration