insulin therapy in non-diabetic adults with cystic fibrosis

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To investigate the effect of low-dose long acting insulin therapy on nutritional status in adult CF patients without diabetes.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders congenital
Study type	Interventional

Summary

ID

NL-OMON38361

Source
ToetsingOnline

Brief title
insulin in CF without CFRD

Condition

- Respiratory disorders congenital
- Appetite and general nutritional disorders

Synonym
cystic fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: eigen vakgroep;CF vereniging

Intervention

Keyword: Cystic fibrosis, insulin, malnutrition

Outcome measures

Primary outcome

body weight and body mass index.

Secondary outcome

Serum pre-albumin/ESR/leucocytes/CRP/vitamin A,D,E,K

pulmonary function

number of pulmonary exacerbations

antibiotic use

quality of life

foodintake

Study description

Background summary

Chronic malnutrition with weight loss is a major problem in patients with Cystic Fibrosis. There is a clear association between malnutrition and impaired pulmonary and muscle functions, and poorer survival. Nutritional supplementation is often difficult to accompolish. Several therapies to improve nutritional state have been studied, most of them were very shortterm and showed many negative side effects.
Insulin, primarily known as a glucose-lowering agent, is a potent anabolic hormone which acts on a range of carbohydrate, fat and protein metabolisms. Previous studies have suggested that insulin might improve weight and pulmonalry function in CF patients with diabetes. In daily practice we often see CF patients with clinical deterioration 4-5 years before the diagnosis CF-related diabetes. We feel these patients already have hyperglycaemic events more often, resulting in pulmonary infections and declined pulmonary function. We hypothesize that low-dose long-acting insulin will improve nutritional status in CF patients without diabetes.

Study objective

To investigate the effect of low-dose long acting insulin therapy on nutritional status in adult CF patients without diabetes.

Study design

A prospective randomized double-blind placebo-controlled trial.

Intervention

All patients will be randomized for either insulin or placebo.

Study burden and risks

The study period will be 26 weeks for each patient, including 2 weeks run-in period and 24 weeks of therapy. During this period patients will visit the hospital at least 5 times. At each visit patients are seen under fasting conditions in order to give blood and patients will be interviewed and examined physically. During the treatment period patients have to inject themselves subcutaneously, once a day with insulin/placebo. We ask patients to keep up a diary with bloodglucose levels, insulin dosage and intake. Before and after the study period pulmonary function will be measured and patients have to answer a validated quality of life questionnaire for CF patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients aged 18 years diagnosed with cystic fibrosis, a normal or impaired glucose tolerance test, exocrine pancreatic insufficiency, BMI <21.

Exclusion criteria

pregnancy, pregnancy wish, lactation, history of organ transplantation, high urgency status on waiting list for transplantation, use of systemic corticosteroids within one month before or during the study period, malignancy, distal intestinal obstruction syndrome (DIOS) or pulmonary exacerbation with hospital admission one month before or during the study period, use of appetite stimulants, BMI >30.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2012
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lantus
Generic name:	glargine
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	placebo
Generic name:	placebo

Ethics review

Approved WMO Date:	07-02-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	22-05-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2011-001916-69-NL
CCMO	NL36694.098.12