A placebo-controlled trial of insulin therapy with or without adjuvant metformin in patients with Cystic Fibrosis-Related Diabetes

Published: 28-01-2009
Last updated: 06-05-2024

Investigate the effect of adjuvant metformin therapy on insulin need and on glycaemic control in CFRD patients.

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

Summary

ID

NL-OMON38078

Source
ToetsingOnline

Brief title
Insulin therapy and adjuvant metformin in CFRD

Condition

- Respiratory disorders congenital
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Cystic Fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

Source(s) of monetary or material Support: Eigen vakgroep

Intervention

Keyword: Cystic fibrosis-related diabetes (CFRD), Insulin, Metformin

Outcome measures

Primary outcome

Insulin need in number of units per day and blood HbA1c levels.

Secondary outcome

Results from a three-day continuous glucose monitoring, body weight, and

overall clinical status, expressed as pulmonary functions, number of pulmonary

exacerbations, and antibiotics use.

Results from a validated quality of life questionnaire for CF patients.

Insulin sensitivity determined by HOMA-IR.

Study description

Background summary

Diabetes is a major co-morbidity in patients with Cystic Fibrosis (CF) with a prevalence of 31% in our adult patient population. Cystic fibrosis-related diabetes (CFRD) consists of both insulin deficiency and insulin resistance and is increasing with age. It is associated with deterioration in overall clinical status and shorter life expectancy, presumably due to a higher susceptibility to develop pulmonary infections. Therefore it is important to aim towards perfect glycaemic control.
The recommended treatment in CFRD is insulin therapy. Still the diabetes is difficult to control due to the fluctuating insulin resistance during pulmonary exacerbations. We hypothesize that by adding an oral glucose-lowering agent to insulin therapy a better overall management of CFRD can be accomplished.

Study objective

Investigate the effect of adjuvant metformin therapy on insulin need and on

glycaemic control in CFRD patients.

Study design

Prospective randomised double-blind crossover placebo-controlled study.

Intervention

All patients will be randomised for either first receiving adjuvant metformin or first receiving placebo during the first therapy period. The metformin dosage will be weight-dependant. For the second therapy period patients will interchange to the other therapy regimen, either metformin or placebo.

Study burden and risks

The total study period for each subject comprises 32 weeks, i.e. a 4-weeks run-in period, a 12-weeks treatment period, a 4-weeks wash-out period and the second 12-weeks treatment period. During the study the patients will visit the outpatient clinic with a minimum of 9 times, spread out over the total study period. At each visit, patients are fasting in order to give blood. They will undergo physical examination and will be questioned about their present clinical status. During the two treatment periods, patients have to take either the metformin tablets or placebo tablets with a maximum of 4 tablets a day. During the study patients are asked to do regular glucose serial self-monitoring blood glucose testing and to keep up a diary with their glucose levels and insulin usage. A continous glucose monitoring for three days will be performed during both periods. At the end of both treatment periods patients are asked to make a standardized 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

Adult cystic fibrosis patients (> 18 years)
Diagnosed with cystic fibrosis-related diabetes for at least 6 months

Exclusion criteria

Pregnancy
Pregnancy wish
Lactation
Organ transplantation in past
On waiting list for transplantation
Proven cystic fibrosis related liver disease or other hepatic disease
Proven type 1 diabetes mellitus
Patients with increased risk on lactate acidosis
Renal insufficiency (creatinine clearance < 50 ml/min (Cockcroft gault))
Sepsis
Alcohol abuse
Use of ACE-inhibitors
Severe cardiovascular disease
Permanent oxygen use
FEV1 % predicted <30 %
BMI < 19

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	metformin HCL
Generic name:	metformin HCL
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	placebo
Generic name:	placebo

Ethics review

Approved WMO

Date:	28-01-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	11-03-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	15-05-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	10-07-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2009-009875-37-NL
CCMO	NL24616.098.09