Continuous Glucose Monitoring System in patients with Cystic Fibrosis

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Investigate the CGMS results in comparison with an OGTT and one-day self monitoring of blood glucose. Thereby compare the glucose patterns of patients with an impaired glucose tolerance to patient with a normal glucose tolerance and CFRD.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON31821

Source
ToetsingOnline

Brief title
CGMS in CF

Condition

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

Synonym
Cystic fibrosis and diabetes

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Vanuit eigen vakgroep

Intervention

Keyword: Continuous Glucose Monitoring System, Cystic Fibrosis, Cystic Fibrosis-related diabetes

Outcome measures

Primary outcome

Glucose values during a three-day period extracted by the CGMS and the blood

glucose levels of a one-day blood glucose self-monitoring.

Secondary outcome

Not applicable

Study description

Background summary

The most common complication in Cystic Fibrosis (CF) is Cystic Fibrosis-Related Diabetes (CFRD). An oral glucose tolerance test (OGTT) is recommended for diagnosing CFRD. The continuous glucose monitoring system (CGMS) is a relatively new instrument to measure subcutaneous glucose levels. This may give additional information in the diagnosis and understanding of CFRD.

Study objective

Investigate the CGMS results in comparison with an OGTT and one-day self monitoring of blood glucose. Thereby compare the glucose patterns of patients with an impaired glucose tolerance to patient with a normal glucose tolerance and CFRD.

Study design

Prospective clinical comparing study

Study burden and risks

The total scope of the study comprises maximum four days. On the first day patienets are admitted into the hospital for 2 hours. At this visit, they will undergo physical examination by determination of body temperature, blood

pressure and pulses and will be questioned about their present clinical status. A glucose sensor is placed subcutaneously on the abdomen. After one hour, the sensor will be calibrated. Each day four random blood glucose levels have to be charged in the sensor to calibrate itThe sensor remains for three days. On day two, patients are asked to do a one-day blood glucose self-monitoring with 7 monitoring moments, i.e. fasting, before en one hour after each meal, and before bedtime. After the three-day period patients can remove the sensor by themselves and return it within a few days to the hospital. The sensor will be read out retrospectively.

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

1. Cystic fibrosis

2. > 18 years

Exclusion criteria

1. Exocrine pancreas sufficiency
2. Former Cystic fibrosis-related diabetes diagnosis
3. Organ transplants
4. Pregnancy
5. Use of medication interfering with glucose tolerance
6. Recent pulmonary exacerbation, requiring antibiotic therapy within past 4 weeks
7. Too short follow-up period of CGMS (< 24 hours)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2008
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	24-11-2008
Application type:	First submission
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
CCMO	NL21343.098.08