Oral glucose tolerance test with prolonged determination of glucose, insulin and C-peptide levels in patients with Cystic Fibrosis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22533

Source
NTR

Brief title
Prolonged OGTT in patients with CF

Health condition

Cystic Fibrosis
Oral glucose tolerance test
Diabetes

Sponsors and support

Primary sponsor: Initiator
Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

Blood glucose levels, blood insulin levels and blood C-peptide levels during OGTT and after OGTT during a follow-up period of 3 hours.

Secondary outcome

Insulin resistance and ß-cell function, calculated respectively by HOMA-IR and HOMA-B.

Areas under the curve for glucose, insulin and c-peptide levels.

Peak glucose levels.

Study description

Background summary

Rationale: In literature the value of early diabetic therapy in patients with Cystic Fibrosis (CF) developing diabetes is considered of major interest. Still, no consensus is available on the optimal diabetic treatment of CF patients with either a normal or impaired glucose tolerance. To get more insight in the exact glucose levels and the total insulin secretion, as well as to determine the optimal time of measurement peak glucose levels we would like to perform prolonged oral glucose tolerance test (OGTT) with insulin and C-peptide measurements in these patients, from what areas under the curve, insulin resistance and ß-cell function will be calculated
Objective: Investigate the exact glucose levels during a two hour OGTT and a follow-up period of three hours. At the same time, insulin and C-peptide levels are determined to get more insight in the total insulin secretion.

Study design: Prospective clinical comparing experiment with defined patient populations.

Study population: The patient population comprises 6 adult CF patients with exocrine pancreas sufficiency, 6 adult CF patients with exocrine pancreas insufficiency and a normal glucose tolerance, and 6 adult CF patients with exocrine pancreas insufficiency and an impaired glucose tolerance.

Main study parameters/endpoints: Blood glucose levels and blood insulin levels and blood C-peptide levels during an 2 hour OGTT and during a follow-up period of 3 hours. Samples are taken on pre-set times.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjects will have to visit our clinic one time in the total scope of this study. 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 venflon is placed in an antecubital vein and will stay in place during the total 5 hours. During this period of 5 hours, subjects have to stay sober. A total of 10 blood samples of each 4,0 ml

will be taken.

Study design

The study period for the individual patient comprises one outpatient visit of 6 hours.

Intervention

All subjects included into this study will be administered in the hospital after three days of high carbohydrate intake and an overnight fasting of at least 8 hours. Subjects will be questioned about their present clinical status. In all subjects temperature, pulses and blood pressure will be determined.

After a 15-min period of acclimatizing, a venflon is placed in an antecubital vein. A glucose solution of 1,75 gr/kg with a maximum of 75 grams of glucose is orally administered to the subjects. Blood samples of 4,0 ml each in a serum tube are taken on pre-set times, i.e. -5, 0, 30, 60, 90, 120, 150, 180, 240, and 300 min after administering the glucose solution. Patients stay sober during the total scope of the study.

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Eligibility criteria

Inclusion criteria

1. Cystic Fibrosis patients

2. Proven diagnosis cystic fibrosis: either positive genotyping or raised sweat sodium

3. > 18 years

4. Stable disease

5. Regularly attending outpatients clinic

Exclusion criteria

1. Absent oral glucose tolerance test in last half year

2. Cystic fibrosis-related diabetes diagnosis

3. Organ tranplantation in history

4. Pregnancy

5. Current use of medications interfering with glucose tolerance

6. Current or recent pulmonary exacerbation requiring oral or intravenous antibiotics in the past 4 weeks

7. Medical conditions other than cystic fibrosis interfering with glucose tolerance

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2008
Enrollment:	18
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-05-2008
Application type:	First submission

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
NTR-new	NL1267
NTR-old	NTR1313
Other	METC Zuidwest Holland : 08-005
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A