Performance and patient acceptance of a commercially available beverage as compared to an oral glucose solution for oral glucose tolerance tests in cystic fibrosis (CF) patients who are screened for CF-related diabetes.

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Primary Objective: To compare the performance of a glucose tolerance test (*AATT*) with a commercially available beverage to the results of the conventional OGTT with respect to diagnosing IGT and CFRD in patients with CF. Secondary Objective(s): To...

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

Summary

ID

NL-OMON51410

Source
ToetsingOnline

Brief title
CF-OGTT study

Condition

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

Synonym
CF, Cystic fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CFRD, Cystic Fibrosis, OGTT

Outcome measures

Primary outcome

Serum glucose levels at 120 minutes after ingestion of either the standard glucose solution or the sportsdrink.

Secondary outcome

- Serum glucose levels at 30, 60 and 90 minutes after ingestion of either the standard glucose solution or AA drink.

- Patient satisfaction for the ingested test product using a VAS on the following points: overall satisfaction (very dissatisfied - very satisfied), taste (really bad - really good), ease of drinking (very difficult - very easy) and side effects after drinking (e.g. nauseousness, stomach ache) (very little - a lot)..

- The percentage of patients with either CFRD or IGT according to results of either AATT of OGTT.

- The optimal cut-off levels for the AATT using OGTT as a reference standard

Study description

Background summary

Cystic fibrosis (CF) is an incurable genetic disease that affects the pulmonary system, digestive system, reproductive system and the sweat glands.
One of the common comorbidities in CF is pancreatic insufficiency (PI), it affects 85% of the CF population. Pancreatic insufficiency expresses itself in enzymatic deficiencies (exocrine insufficiency) and insulin deficiency (endocrine insufficiency). The insulin deficiency in its turn can cause cystic fibrosis related diabetes (CFRD) after a pre-diabetic state called impaired glucose tolerance (IGT). CFRD is a unique form of diabetes and is extremely common in CF patients, it is occurring in 40-50% of adult CF patients. CFRD does not only affect patients nutritional status, it also leads to pulmonary decline and earlier mortality as compared to patients without CFRD. Early insulin therapy appears to revers some of the decline found with CFRD. Therefore it is recommended to screen for CFRD yearly so it is caught in an early stadium. For screening the oral glucose tolerance test (OGTT) or the glucose challenge test is used. During the OGTT fasting patients have to drink a 300 ml solution that contains 75 grams of glucose following an overnight fast. The solution has to be finished in 15 minutes. Then the blood glucose level is measured at 0 minutes and 120 minutes. CFRD is diagnosed when the fasting glucose level is is higher or equal to 7mmol/L or the 120 minutes glucose level is higher or equal to 11.1 mmol/L. IGT is diagnosed when the glucose level after 120 minutes is > 7.8 mmol/L and <11.1 mmol/L.

The OGTT is perceived as uncomfortable by patients. The glucose solution makes patients nauseous and can even cause vomiting. This leads to patients refusing to undergo the OGTT and being diagnosed with CFRD in a later stadium. The current AMC database for CF patients consisted in 2020 of 127 patients. Of 127 adult CF patients in Amsterdam UMC, 42 patients have known CFRD. Of the remaining 85, 50 patients have exocrine pancreatic insufficiency for which they take pancreatic enzyme suppletion. This group is most at risk to develop CFRD or a disturbance in their glucose metabolism, so they would have the most benefit from a yearly OGTT. However, only 19 (38%) of these patients underwent an OGTT in 2020 and -although the reason for abstaining from this test is not recorded, we know by experience that a percentage of these patients refuses to be tested because they feel aversion against taking the glucose solution. In 2019 the database consisted of 121 patients, of which 78 have no known CFRD yet and 48 of these have exocrine pancreatic insufficiency for which they take pancreatic enzyme suppletion. Again only 19 (40%) of those patients underwent an OGTT.

Therefore, to increase patients adherence in yearly screening for CFRD using the OGTT, for this study the glucose solution is substituted with a commercially available beverage (AA-drink). The hypothesis is that results of this *AATT* will be comparable to the standard OGTT with respect to diagnosing CFRD and IGT. Furthermore we believe that the *AATT* will be better tolerated

by this patient group leading to an increase in patient adherence to our yearly CRFD screening.

Study objective

Primary Objective: To compare the performance of a glucose tolerance test (*AATT*) with a commercially available beverage to the results of the conventional OGTT with respect to diagnosing IGT and CFRD in patients with CF.
Secondary Objective(s): To compare patient satisfaction using a prespecified scoring system for the *AATT* as compared to the conventional OGTT.

Study design

The study will have the set-up of a randomized cross-over trial.
Participants will be patients diagnosed with CF from the outpatient clinic from the Amsterdam UMC - location AMC. The study consists of 2 visits; one visit patients will undergo the standard OGTT, the other visit patients will undergo the OGTT substituting the glucose solution with a commercially available beverage, AA-drink (united soft drinks, the Netherlands) (AATT).
Tests will be performed at the AMC and will take up a proximally 2.5 hours per visit.
Participants will be patients diagnosed with CF from the outpatient clinic from the AMC. Patients have to be at least 18 years old and both women and men will be included. For this study patients will be divided in two subsets of CF patients; those who are not diagnosed with CFRD yet and those already diagnosed with CFRD or a disturbed glucose tolerance. Since we approach patients that already have to come to the hospital to do their yearly screening using the OGTT for the first group, they only have to visit 1 extra time to undergo the AATT. The second group will have to come to the hospital 2 times, first for the OGTT and the second time for the AATT. In both groups the visits need to be at least 2 weeks apart. For both visits patients will have to be fasting before they undergo either the OGTT or the AATT. The fasting starts at 22:00 the evening before the test. Patients who are using insulin will be asked to not inject any short-acting insulin after 23:59 the evening before the test.
Patients will present at the hospital at 08.30. An I.V. cannula will be placed because blood samples have to be taken 5 times to determine the blood glucose level at different time points. The use of the I.V. cannula will make the test more comfortable for the patient. Patients will be randomly assorted to either undergo the OGTT first and 2 weeks later the AAGTT or the other way around.
During one visit patients get to drink a 75 gram glucose solution (OGTT) of 300 ml in 15 minutes. Then their blood will be taken using the I.V. cannula at 0 minutes, 30 minutes, 60 minutes, 90 minutes and 120 minutes to determine the glucose levels.
For the other visit the study set up is the same, the only difference is that patients get to drink 500ml of AA-drink (AATT) instead of the glucose solution. Patients will have to finish this in 15 minutes as well. How long it takes them

to drink the sports drink will be monitored to see if it is easy to do in 15 minutes.
During the test patients will be asked to score the glucose solution or the sports drink using a visual analogue scale. The points patients will have to score the beverages on are: overall satisfaction (very dissatisfied - very satisfied), taste (really bad - really good), ease of drinking (very difficult - very easy) and side effects after drinking (e.g. nauseousness, stomach ache) (very little - a lot).

Study burden and risks

For the group that is already diagnosed with CFRD there is no personal direct benefit with participation in this study. However, there is a possibility of future comfort for other patients who have to undergo an OGTT. For the group that is not diagnosed with CFRD there is a personal benefit because they still have to get screened yearly.
The study consists of minor risks for the patients. Phlebitis is a possible risk due to the I.V. and hyperglycaemia is a possible risk for the patients who have to stop their short-acting insulin.
The study only takes 2 weeks for a patient and for the group that already has to do the annual screening for CFRD it only takes 1 extra visit to the hospital.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age >= 18
- Diagnosed with CF
- One of the following: Diagnosed with CFRD or IGT based on a raise fasting glucose level or OGTT. Or; pancreatic insufficiency, without CFRD

Exclusion criteria

- Age < 18
- Active infection or inflammation
- Use of medication known to affect insulin secretion or insulin resistance, other than short-acting insulin.
- No informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-02-2022

Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	15-02-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL79718.018.21