The physiological role of bile acid‐mediated glucagon‐like peptide‐1 release in humans: The Cerebrotendinous Xanthomatosis Mixed Meal Test study.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23193

Source
NTR

Health condition

diabetes, insulin resistance

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Glucose, bile acids and incretins during meal test.

Secondary outcome

Energy expenditure.

Study description

Background summary

Bile acids (BAs) have traditionally been regarded as nutrient-emulgators but may play an important role in energy metabolism. Primary bile acids are secreted in the bile and are dehydroxylated by the bacterial flora in the colon to form the secondary bile acids. BAs may stimulate the production of glucagon-like peptide-1 (GLP-1) that stimulates insulin secretion and inhibits glucagon secretion in the pancreas in a glucose-dependent fashion. Additionally, it reduces gastrointestinal motility and appetite. Cerebrotendinous xanthomatosis (CTX, OMIM #213700) is an autosomal recessive disorder characterized by a deficiency of sterol 27-hydroxylase leading to a defective BA synthesis (decreased amount of the BA chenodeoxycholate (CDCA)). It is not known whether CTX patients exhibit physiological deficiencies with regard to
postprandial plasma GLP-1 responses, glucose uptake, free fatty acid (FFA) suppression and plasma insulin levels. Studying postprandial glucose metabolism in these patients will provide insight in the metabolic role of BAs. We hypothesize that CTX patients, when untreated, have lower postprandial GLP-1 and insulin levels with higher plasma glucose and FFA levels compared to matched healthy control subjects.

Thus, the primary aim of the present protocol is to determine the role of chenodeoxycholate for postprandial GLP-1 responses (and the resulting metabolic consequences) in humans.

Study objective

We hypothesize that CTX patients, when untreated for a short period, differ from matched healthy controls in the response to a test meal. CTX patients are expected to have lower postprandial GLP-1 and insulin levels with higher plasma glucose and FFA levels.

Study design

One occoasion, 3hr meal test.

Intervention

Mixed meal test: Liquid meal test (standard protocol) during which blood withdrawals are taken for 2-4 hours to measure glucose, insulin, bile acids and incretins.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria, CTX patients:

1. Adult age (older than 18 years of age);

2. Body mass index 19-30 kg/m2;

3. General good health (normal liver and renal function);

4. HbA1c below 7%;

5. Ability to give informed consent.

Inclusion criteria, matched controls:

Matched to CTX patients on individual basis. Preferably, these controls are unaffected healthy relatives to prevent differences in environmental factors (diet, faecal microbial composition,

activity). If this is not possible, healthy matched control (age, length, height, gender) will be recruited.

Exclusion criteria

Since CTX is a rare disorder, little exclusion criteria exist. However, patients that use medication that interferes with glucose metabolism such as oral antidiabetic medication or insulin are not included.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2011
Enrollment:	28
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL2595
NTR-old	NTR2723
Other	MEC AMC : 2011_036
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A