Variance and reproducibility of the postprandial bile acid response

Published: 09-10-2015
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To assess the reproducibility of the postprandial bile acid response as an outcome of metabolic testing.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON43657

Source
ToetsingOnline

Brief title
TRIPLO

Condition

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

Synonym
diabetes, insulins resistance

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: het Diabetes Fonds

Intervention

Keyword: Bile acid metabolism

Outcome measures

Primary outcome

postprandial bile acid concentrations expressed as AUC, max peak, time-to-peak

Secondary outcome

postprandial concentrations of the glucose, lipid and thyroid metabolism

expressed as AUC, max peak, time-to-peak. gastric emptying rate.

Study description

Background summary

Type 2 diabetes mellitus is a growing burden on health worldwide. Recently, bile acid metabolism and signalling have
been shown to have positive effects on glucose metabolism in animal models of metabolic disease. This makes bile
acid research an interesting new avenue in the search for new therapeutic strategies in diabetes management. We
have previously used the postprandial bile acid response as an outcome of metabolic testing, but noticed quite some variability.

Study objective

To assess the reproducibility of the postprandial bile acid response as an outcome of metabolic testing.

Study design

Observational study

Study burden and risks

Burden: 3x6 hours spent at study site, 3x overnight fast, 3x placement of IV cannula, 300 ml blood drawn total.
Risks: placement of IV cannula risks flebitis and hematoma

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

healthy young male
age > 18
BMI < 25

Exclusion criteria

Use of any medication
History of cholecystectomy or other bile duct abnormalities
blood chemistry indicating renal or liver disease

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2016
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO Date:	09-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-11-2016
Application type:	Amendment
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	NL54162.018.15