SitzMARK Evaluation of Reproducibility

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON42885

Source
ToetsingOnline

Brief title
MARKER

Condition

- Gastrointestinal conditions NEC
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Intestinal transit time, Metabolic syndrome, Reproducibility, Sitzmark capsules

Outcome measures

Primary outcome

intestinal transit time measured by SITZMARK-method

Secondary outcome

inflammatory parameters and gut microbiota composition

Study description

Background summary

In the FEBALIGO-trial (43964) we have shown that intestinal transit time is transferrable by fecal microbiota transfer from a donor. However, some doubt remains about the validity of our findings, as this may be explained by 'regression to the mean', because of the strong statistical correlation between baseline intestinal transit time and effect direction (faster or slower) and size after treatment. Futhermore it is not known whether intestinal transit time is different in our study population (metabolic syndrome patients) versus healthy controls.

Study objective

In this small study we want to show that two sequential measurements of intestinal transit time by SITZMARK-method will provide strongly correlated results. In this way we hope to ascertain that regression to the mean did not play a role in the observed effects in our FEBALIGO-study population. Futhermore we will assess whether intestinal transit time is different between metabolic syndrome patients and healthy controls.

Study design

10 test subjects with metabolic syndrome and 10 healthy lean subjects will undergo measurement of the intestinal transit time 2 times in a period of 2 weeks (without intervention). They will take a SITZMARK-capsule on 3 consecutive days and undergo an abdominal X-ray on the day before the first capsule (only in week 2) and on the day after the 3rd to count the markers and determine the intestinal transit time. The baseline X-ray is in week 2 is necessary to rule out a carry-over effect (markers from week 0 that are still in situ in week 2).

Study burden and risks

This study will cost 2 hrs. During/after the visits participants will take a total of 6 capsules in 6 days, 2 blood samples, 2x3 fecal samples, 3 abdominal X-rays and they will fill out a food diary for 7 days (2 times). There is the risk of a bruise and radiation-dose associated risks. Study participants health will not benefit.

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

Male obese subjects with metabolic syndrome (n<=10): 18 to 70 years-old; body mass index (BMI) 30kg/m2 or above with at least 3 out of 5 NCEP metabolic syndrome criteria (fasting

plasma glucose * 5.6 mmol/l, triglycerides * 1.7 mmol/l, waist-circumference > 102 cm, HDL-cholesterol < 1.03 mmol/l, blood pressure * 130/85 mmHg). Patients should be able to give informed consent and be on a stable diet.;Healthy control subjects: 18-69 jr oud, BMI 18,5-25m²/kg. 0/5 NCEP criteria for metabolic syndrome.

Exclusion criteria

Cholecystectomy, use of medication including PPI and antibiotics past three months, (expected) change of diet, episode of diarrhea during study period. irritable bowel syndrome-like complaints.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-11-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	11-10-2016
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	NL58461.018.16