DUPLO study: Comparison of the microbial composition of the upper gastrointestinal tract in lean and obese subjects

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Primary Objective: To investigate the differences in microbiota composition in the upper GI tract between lean and obese subjects. Secondary Objectives: To compare the total bacterial count measured by qPCR in SI samples of lean versus obese...

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

Summary

ID

NL-OMON42930

Source
ToetsingOnline

Brief title
DUPLO-study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Danisco Sweeteners Oy

Source(s) of monetary or material Support: Danisco Sweeteners Oy;Finland

Intervention

Keyword: IntelliCap®, microbiota, obesity, small intestine

Outcome measures

Primary outcome

Differences in microbiota composition in the upper GI tract between lean and obese subjects.

Secondary outcome

Total bacterial count measured by qPCR in SI samples of lean versus obese subjects; biomarkers measured in blood (fasting) at baseline and on the sampling day: glucose, insulin, cholesterol, IL-1, IL-6, TNF-a, in relation to microbiota composition.

Study description

Background summary

The microbial composition in the small intestine (SI) differs largely from the composition in feces. Many physiological processes related to health, such as immunoregulation and metabolic programming, mainly take place in the SI. Therefore, the SI, from a microbiota perspective, is as relevant as the large intestine. There are indications that microbiota composition is different in lean and obese subjects, and is related to insulin resistance. However, these indications are mainly based on the analysis of fecal samples. Therefore, analysis of the microbiota composition in the more proximal part of the gastrointestinal (GI) tract may provide new insights into the microbial species that are involved or related to metabolic homeostasis at that location. The IntelliCap® CR system offers a minimally invasive tool that is able to collect reliable samples in the SI, as was shown by NIZO in a clinical validation study. The main aim of the current study is to explore and compare the upper GI microbiota composition in lean and obese subjects, in order to generate new leads for development of products that may target the upper GI microbiota community or specific species thereof, which may impact the maintenance of

metabolic homeostasis. This may provide new opportunities for the treatment, reduction or prevention of overweight and/or obesity or insulin resistance.

Study objective

Primary Objective: To investigate the differences in microbiota composition in the upper GI tract between lean and obese subjects.
Secondary Objectives: To compare the total bacterial count measured by qPCR in SI samples of lean versus obese subjects, and to analyze the relationship between the microbiota composition and the total bacterial count, biomarkers measured in blood (fasting; insulin, glucose, cholesterol, IL-1, IL-6, TNF-a), and descriptive measures (weight, BMI, stool frequency).

Study design

The study is designed as a parallel observational study, comparing the upper GI microbiota composition in lean and obese subjects.

Study burden and risks

The burden of the subjects that participate in this study consist of investing 10 hours in total for screening, blood sampling, fully controlled diet, sampling day with IntelliCap capsule intake, and fecal sample collection. Participants will not directly benefit from the study. The study needs to be performed in lean and obese subjects. There are minor risks for the participants during the study. All foods and drinks provided as controlled diet are commercially available and composed by professional dieticians of Wageningen University. The CE certified IntelliCap® CR system, used as minimally invasive sampling device and validated in humans, is safe and well tolerated. If the IntelliCap® capsule is not recovered from the feces within 7 days after administration, an abdominal X-ray will be performed to check if the IntelliCap® capsule is still within the body. For the quencher, present in the IntelliCap® capsule, thorough safety reports have been written, showing that the doses used in the capsule are safe for human application.
Based on these considerations, to our opinion, the risks for participation in this study are negligible, and we have made every effort to minimize potential risks. Therefore, we feel that the remaining risks are acceptable and do not outweigh the scientific relevance of this study.

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

* Female
* Age: 25-50y; In case of sufficient eligible subjects, the age distribution of the two groups will be aligned, and the age range will be reduced to max. 10 y between highest and lowest age.
* Lean: BMI 19-23 kg/m2, waist circumference <80 cm, and fasting glucose <6.1 mmol/L; Obese: BMI 30-35 kg/m2, waist circumference >88 cm, and fasting glucose ><=6.1 and <7.5 mmol/L
* Healthy as assessed by the NIZO lifestyle and health questionnaire (*Verklaring leefgewoonten en gezondheid*)
* Healthy as assessed by results of the pre-study safety laboratory tests (clinical chemistry: liver/kidney function etc).
* Regular and normal Dutch eating habits as assessed by the NIZO lifestyle and health questionnaire (3 main meals per day)
* Regular bowel movement (defecation on average once a day, at least 4 times/week)

Exclusion criteria

* Participation in any clinical trial with oral, intravenous or inhalatory administration of any substances during 90 days before study start
* History or presence of any clinically important disease or disorder which, in the opinion of the Investigator, may either put the subject at risk because of participation in the study, or influence the results or the subject*s ability to participate in the study:
o type 1 or type 2 diabetes
o gastrointestinal disease
o bariatric surgery
o cardiovascular disease, liver or renal failure or disease of kidney or thyroid gland, cancer
o infectious disease, history of chronic active inflammatory disorders, food allergy
* Use of antibiotics during the one (1) year prior to study start: if this criterion restricts inclusion too much, we will lower this timeframe to six (6) months.
* Constipation/infrequent bowel movement (defecation <4 times per week)
* Having diarrhea within 3 months prior to the study start
* Use of laxatives, fiber supplements (e.g. lactulose), glucose lowering drugs, insulin, anti-obesity drugs, immunosuppressive drugs (e.g. systemic corticosteroids, cyclosporine, azathioprine, antibodies) during the three (3) months prior to study start
* Use of temporary or irregular medication for diabetes, dyslipidemia or hypertension
* Use of any prescribed or non-prescribed medication (other than paracetamol) including antacids, analgesics, H2 receptor antagonists, proton pump inhibitors, herbal remedies or anti-inflammatory drugs (e.g. NSAIDs) during the three (3) weeks prior to study start.
* Use of pro- or prebiotics during the three (3) months prior to study start
* Mental status that is incompatible with the proper conduct of the study
* Presence of swallowing or passage disorder
* Carrying a pacemaker or any other (implanted) medical electronic device
* Scheduled for an MRI scan during the study period
* Not willing to have an X-ray if the capsule is not recovered from the faeces
* Alcohol consumption > 15 units/week and >3/day, and/or not willing to stop during the study
* Drug abuse, and not willing/able to stop this during the study
* Heavy exercise or sports training > 10 hours/week
* Smoking
* Active or recent participation in a weight loss program including weight change (increase or loss) of >3 kg during the last three (3) months
* Reported unexplained weight loss or weight gain of > 5 kg in the year prior to pre-study screening
* Reported slimming or medically prescribed diet
* Reported special diets such as vegetarian, vegan, macrobiotic, low carbohydrate, dairy-free, or diets with intention to use certain limited food groups only (e.g. paleo diet, egg-grape diet)
* Pregnant or planning to become pregnant during the study, breastfeeding (subjects will be asked to perform a urine pregnancy test on the study day, before swallowing the caspule)
* Postmenopausal women on unstable hormone replacement therapy (periodical hormone treatment such as contraceptives is no exclusion criterion)

* Not willing to accept information-transfer concerning participation in the study, or information regarding health, like laboratory results, findings at anamnesis or physical examination and eventual adverse events to and from his general practitioner

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-04-2017
Enrollment:	22
Type:	Actual

Medical products/devices used

Generic name:	IntelliCap® system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	14-02-2017
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL59327.081.16