MICRO-study:
Is the IntelliCap® system a suitable tool to study changes in the small intestinal microbiota?

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42238

Source
ToetsingOnline

Brief title
MICRO-study

Condition

- Other condition

Synonym
bacterial gutflora, microbiota composition

Health condition

Effect of diet on microbiota composition in the small intestine

Research involving

Human

Sponsors and support

Primary sponsor: NIZO food research BV
Source(s) of monetary or material Support: Ministerie van OC&W,NIZO food research;EFRO subsidie

Intervention

Keyword: IntelliCap®, microbiota, minimally-invasive, small intestine

Outcome measures

Primary outcome

Safety and tolerability of the IntelliCap® system when used as a gastrointestinal fluid sampling device, as assessed by reporting adverse events (AE) and serious adverse events (SAEs) that occur during the study along with their severity and potential relationship to the IntelliCap® system.

Small intestinal microbiota composition after the 2 dietary intervention periods, analysed by 16S pyrosequencing.

Secondary outcome

Small intestinal microbiota composition as compared to the faecal microbiota composition, analysed by 16S pyrosequencing.

Study description

Background summary

The gut microbiota is involved in the regulation of multiple host metabolic and immune pathways. So far, studies on human microbiota are almost exclusively based on the analysis of fecal samples. Short-term exposure to extreme diets (high protein versus high carbohydrate) can induce rapid changes in fecal

microbiota. However, the microbiota in the small intestine is as relevant for health as in the large intestine. Recently, an electronic medical device, named the IntelliCap® system, was developed for the site-specific delivery of drugs in the gastrointestinal tract. The CE certified IntelliCap® system comprises a capsule-shaped delivery device (IntelliCap® capsule) and ancillary equipment. The IntelliCap® capsule transmits measured data wirelessly to a computer, which enables the real-time measurement of pH and body temperature, allowing for minimally-invasive detection of its location in the gastrointestinal tract. By reversing the delivery mechanism of the device, this capsule has been used to aspirate liquid from its environment. The IntelliCap® system may thus be used as a minimally-invasive tool for the sampling of small intestinal microbiota in humans.

Study objective

The primary objective is to evaluate the safety and tolerability of the IntelliCap® system when used as a gastrointestinal fluid sampling device will be evaluated.
Another primary aim is to evaluate the IntelliCap® system as a tool to study changes in small intestinal microbiota composition in humans in vivo. We will do this by studying the impact of a high protein or high carbohydrate diet on microbial composition in the small intestine.

Secondary objective is to compare the faecal microbial composition to the microbial composition in the small intestine.

Study design

Randomized cross-over controlled feeding trial. Two diets will be used: a high-protein diet versus a high-carbohydrate diet given for three days. Volunteers will also receive a three day medium protein/medium carbohydrate before (run-in diet) and in between the intervention diets (wash-out diet). The IntelliCap® capsule will be administered at the end of both intervention periods. In short: after an overnight fast, subjects will ingest the IntelliCap® capsule with water. Subjects will receive a breakfast after the passage of the capsule from the stomach to the duodenum (around 30 to 60 min; based on on-line measurement of change in pH). A luminal sample will be taken in the small intestine when the capsule reaches the ileum (around ~3h; based on on-line measurement of change in pH). After ingestion, subjects need to collect all faeces until excretion and recovery of the capsule (around 24-48 h after swallowing). Participants will report any adverse events to the study team.

Intervention

A high-protein/low-carbohydrate diet (26,7E% protein, 38.2E% carbohydrate), a

low-protein/high-carbohydrate diet (7E% protein, 59.6E% carbohydrate).

Study burden and risks

Subjects that participate in this study will invest approximately 20 hours. There are minor risks for the participants during the study. There is no evidence that the controlled diets in the intervention are unsafe. All foods and drinks provided are commercially available and composed by professional dieticians of Wageningen University. The CE certified IntelliCap® system, regularly used in humans for the targeted delivery of substances (drugs), is safe and well tolerated. If the IntelliCap® capsule is not recovered from the faeces within 7 days after administration, an abdominal X-ray will be performed to check if the IntelliCap® capsule is still within the body. Participants will receive ¤200,- for completing the study. Subjects will also receive a repayment of traveling expenditures, with a total maximum of ¤50,-. If reserve participants do not need to replace dropouts, they will receive ¤75,- plus a maximum of ¤25,- travel expenditure repayment for their participation. Furthermore all foods and drinks for 14 days during the intervention trial will be provided for.

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 males
• Age 18-30yrs
• BMI between 20-30 kg/m2
• Regular bowel movement (defecation on average once a day)
• Signed informed consent

Exclusion criteria

• 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 (e.g. diabetes, cardiovascular disease, gastrointestinal disease, renal failure, cancer, infectious disease).
• Presence of swallowing disorder
• Use of any prescribed or non-prescribed medication (other than paracetamol) including antacids, analgesics, and herbal remedies during the three (3) weeks prior to study start.
• Carrying a pacemaker or any other (implanted) medical electronic device
• Scheduled for an MRI scan during the study period
• Tobacco smoker
• Unstable body weight (weight gain or loss >5kg in the past 3 months)
• Use of antibiotics within 2 months of starting the study or planned during the study
• Use of pro- or prebiotics
• Constipation/infrequent bowel movement
• Abuse of drugs/alcohol (alcohol: >4 consumptions/day or >20 consumptions/week)
• Participation in another biomedical study
• Having diarrhoea within 2 months prior to the study start
• Vegetarianism/Veganism
• Allergic for dairy products (milk allergy or lactose intolerance)
• Known or suspected allergy to any product used in this study
• Personnel of Wageningen University, Division of Human Nutrition.
• Current participation in other research from the Division of Human Nutrition
• Not willing to have an X-ray if the capsule is not recovered from the faeces

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2015
Enrollment:	12
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	18-11-2014
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	07-01-2015
Application type:	Amendment
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	NL50518.081.14