Effect of pasteurized Akkermansia muciniphila on maintenance of body weight after a low caloric diet

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51753

Source
ToetsingOnline

Brief title
Akkermansia and weight maintenance

Condition

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

Synonym
insulin resistance, overweight

Health condition

obesity

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: A-mansia,Industry

Intervention

Keyword: akkermansia, weight loss, weight maintenance

Outcome measures

Primary outcome

changes in body weight

Secondary outcome

Changes in body composition, glucose metabolism, insulin sensitivity and

metabolic health by evaluation the following parameters:

- BMI, waist and hip corcumference and body composition (DEXA scan)

- cirulating metabolites, hormones and inflammatory markers

- adipose tissue gene/protein expression

- faecal and circulating SCFA

- faecal microbiota composition

Study description

Background summary

The causal beneficial impact of A. muciniphila on obesity has been demonstrated by a variety of studies in animal models. In the meantime, small-scale human studies provide evidence that pasteurization of A. muciniphila is safe for human use and has great potential to beneficially affect control of body weight and glucose homeostasis in humans. Therefore, in this project we hypothesize that pasteurized Akkermansia muciniphila will be superior to placebo intervention in maintaining body weight after a low caloric diet in participants with overweight or obesity after a

phase of weight loss.

Study objective

In this project we intends to study the efficacy of pasteurized A. muciniphila for protection against weight regain in individuals with overweight/obesity, and aims to address the following key objectives:
1. To investigate the effects of pasteurized Akkermansia muciniphila on the maintenance of body weight after a phase of weight loss.
2. To investigate the effects of pasteurized Akkermansia muciniphila on body composition and body fat distribution, glucose homeostasis and insulin sensitivity and metabolic health.
3. To investigate the effects of pasteurized Akkermansia muciniphila on the faecal bacterial composition and functionality, systemic inflammation, gut barrier function and identify relevant biomarkers

Study design

Double blind, controlled, randomized, parallel design.

Intervention

The participants will first undergo a low caloric diet (LCD, ~900kcal) for 8 weeks. Participants that loss at least 8% of weight will be randomized (with stratification for age and sex) in a weight maintenance period in which they either receive pasteurized Akkermansia muciniphila or placebo for 6 months.

Study burden and risks

Burdens that volunteers can experience, such as the time spent with the study. Also the intake of the products during the LCD and weight maintenance period can be seen as a burden for the participants.
During the LCD, the participants might experience headaches, dizziness, tiredness and nausea might occur due to the reduced energy and particularly carbohydrate intake (particularly in the first few days) during the weight loss period.
Venepunctures can occasionally cause a local hematoma or bruise to occur. Some participants report pain during venepuncture.
During CID 1, 2 and 3 adipose tissue biopsies will be taken. The adipose tissue biopsy might cause local hematoma as well. To minimize the risk for a hematoma, the biopsy place will be compressed for approximately 5 minutes after biopsy. The place of incision will potentially leave a small scar (* 3 mm). To promote good wound healing, the incision will be sealed with sterile steristrips and a waterproof band-aid.

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

Overweight/obese (BMI >= 28 kg/m2 < 40 kg/m2) men and women

Exclusion criteria

- diabetes mellitus
- gastroenterological diseases or major abdominal surgery (allowed i.e.: appendectomy, cholecystectomy)
- lactose intolerance and other digestive disorders
- cardiovascular disease, cancer, liver or kidney malfunction (determined based on ALAT and creatinine levels,
respectively)

- disease with a life expectancy shorter than 5 years
- abuse of products (alcohol consumption > 15 units/week, or any drugs)
- excessive nicotine use defined as >20 cigarettes per day
- plans to lose weight or follow a hypocaloric diet
- regular supplement of pre- or probiotic products
- intensive exercise more than three hours a week
- Use of any medication that influences glucose or fat metabolism, like lipidlowering-drugs (e.g. PPAR γ or PPARα (fibrates) agonists), glucose-lowering agents (including allsulfonylureas, biguanides, α-glucosidase inhibitors, thiazolidinediones, repaglinide, nateglinide and insulin), inflammation (e.g. anti-inflammatory or immunosuppressive drugs) and anti-oxidants;
- use of laxation products in the last three months or during the study period- Suikerziekte heeft;
- Pregnancy and lactation
-vegan

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-08-2022
Enrollment:	108
Type:	Actual

Ethics review

Approved WMO

Date:	30-05-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-07-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL80563.068.22