A case-control study of oral and gut microbiota, malnutrition and appetite in community-dwelling older adults in the Netherlands

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We aim to determine the differences in oral and intestinal microbial composition between community-dwelling older adults with and without malnutrition, further stratified to those with and without poor appetite.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON47862

Source
ToetsingOnline

Brief title
Microbiota, malnutrition and appetite in older adults (MICMAC).

Condition

- Appetite and general nutritional disorders

Synonym
Malnutrition

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Horizon 2020 EU beurs (project 678732)

Intervention

Keyword: Appetite, Malnutrition, Microbiota, Older adults

Outcome measures

Primary outcome

Main study parameter will be the intestinal microbial composition as determined by 16S RNA-sequencing of frozen faecal samples.

Secondary outcome

We will investigate the oral microbiota as determined by 16S RNA-sequencing of frozen, tongue swabs and salivary samples. We will further determine metabolic, endocrine and inflammatory biomarkers from faecal, salivary and blood samples to investigate the different pathways through which the microbiota influences its host. We will also study the differences in oral microbiota and the relationship with subjects* sense of taste and smell as these might also influence loss of appetite.

Study description

Background summary

Seven to sixteen percent of the community-dwelling older adults is affected by protein-energy malnutrition, posing several health and financial concerns. Although various factors have been proposed to contribute to malnutrition in the older adults, they have failed to lead to effective therapeutic and preventative interventions. A new possible target may be the composition of intestinal microbiota. Microbiota may influence nutritional status and appetite through metabolic, endocrine and inflammatory pathways. We hypothesize that microbial composition will differ significantly between malnourished and well-nourished older adults with and without poor appetite. Determining these differences will be detrimental in developing dietary-based pre- and probiotic

interventional measures.

Study objective

We aim to determine the differences in oral and intestinal microbial composition between community-dwelling older adults with and without malnutrition, further stratified to those with and without poor appetite.

Study design

A case-control study.

Study burden and risks

The current study will be performed in a relatively healthy population. It will not contain an intervention and will not interfere with medical treatment. It will target an important medical issue specific to this population and aims to elucidate pathophysiological pathways responsible for malnutrition. Ultimately, this study is being conducted in collaboration with the PROMISS research consortium, that will use its results to develop new food products, which will become commercially available and will be tailored to the nutritional needs and preferences of the older adults. Therefore, the older adult population as a whole would benefit from our study.
The subjects will be contacted by regular mail, phone and a single home-visit and will not be required to travel. It will concern subjects that have already agreed to participate in the LASA-cohort and are thus familiar with the concept of scientific research. They will be required to fill out a questionnaire and anthropometric and taste measurements will be done. Finally, oromucosal and faecal samples will be obtained. Faecal sampling could be construed as a burden, but does not pose any risks to the subjects* health. The procedure is similar to the national screening program for colon carcinoma. Half of the subjects will participate in further phenotyping consisting of smell tests and salivary and blood sampling. From all study procedures, only blood sampling is invasive. Sampling of peripheral venous blood will be performed once only by a clinically experienced investigator. It carries the risk of hematoma (common, low burden) and phlebitis (rare, low-intermediate burden).

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

Age 65 years and older;
Mentally competent to agree with and participate in study;
Living at home (non-institutionalized);
Participant of the LASA-cohort (Longitudinal Aging Study Amsterdam).

Exclusion criteria

Body-Mass Index of 30 and above;
Active malignancy (with the exception of basal cell carcinoma);
History of inflammatory bowel disease;
Immune suppression (either medicinal or disease-related);
Use of antibiotics three months prior to faecal and salivary sampling;
Long-term admittance (more than 4 weeks) to hospital or long-term care facility in three months prior to faecal and salivary sampling;
Clinical symptoms of acute gastro-enteritis in the two weeks prior to faecal and salivary sampling (i.e. vomiting, acute diarrhoea).

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):	17-07-2017
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	15-06-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-06-2018
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	NL60911.029.17