Effect of Intestinal microbiota transplantation on Satiety and energy metabolism in female patients with Anorexia Nervosa

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24821

Source Nationaal Trial Register

Brief title INSTANT trial

Health condition

anorexia nervosa

Sponsors and support

Primary sponsor: amc Source(s) of monetary or material Support: amc

Intervention

Outcome measures

Primary outcome

the effect of FMT on different microbiota composition in relation to weight, appetite/satiety

1 - Effect of Intestinal microbiota transplantation on Satiety and energy metabolis \ldots 14-05-2025

(fMRI/questionnaires) and Nutrient Drink Test (incl plasma hormones)

Secondary outcome

the effect of FMT on difference in resting energy expenditure (REE), physical activity energy expenditure (PAEE), serotonin metabolism, body composition (Body Impedance Analysis, BIA) and Psychological questionnaires

Study description

Background summary

we aim to identify driving (microbiota related) factors that can improve metabolic control, food intake and subsequent weight gain in anorexia nervosa patients by infusion donor feces

Study objective

Anorexia nervosa (AN) is a psychiatric disease resulting in severely reduced food intake partly due to altered appetite/satiety balance resulting in very low BMI and the highest mortality rate of all mental illnesses1. Several forms of psychological therapies, with or without medication, have been tried, but have not been very successful. The pathophysiology of AN is incompletely understood, but disturbed intestinal microbiota composition might be involved. Since we have previously shown that fecal microbial transplantation (FMT) has an effect on metabolism, we aim to test this intervention in anorexia nervosa patients.

Study design

baseline ,6 and 12 weeks

Intervention

single donor fecal transplantation from female donor with BMI of 25 kg/m2 (allogenic) or own (autologous)

Contacts

Public

AFDELING INWENDIGE GENEESKUNDE AMC
MEIBERGDREEF 9, KAMER F4.159.2 M. Nieuwdorp Amsterdam 1105 AZ

2 - Effect of Intestinal microbiota transplantation on Satiety and energy metabolis ... 14-05-2025

The Netherlands +31 (0)20 5666612 Scientific AFDELING INWENDIGE GENEESKUNDE AMC
 MEIBERGDREEF 9, KAMER F4.159.2 M. Nieuwdorp Amsterdam 1105 AZ The Netherlands +31 (0)20 5666612

Eligibility criteria

Inclusion criteria

- Caucasian female
- Older than 18 years
- BMI <17 kg/m2
- Stable medication use
- Meeting the DSM V criteria for anorexia nervosa, restricting type
- able to give informed consent

Exclusion criteria

- PPI and antibiotics use in last 3 months
- Smoking, XTC, amphetamine or cocaine abuse
- Alcohol abuse (>3/day)

- A concomitant severe psychiatric disorder, such as psychosis, severe depression or a personality disorder that renders them unsuitable for the trial as judged by a psychiatrist

- Participation in a research protocol involving radiation exposure in the last 2 years.
- Contraindication MRI (pregnancy, pacemaker and metals contraindicated for MRI).
- Cholecystectomy
 - 3 Effect of Intestinal microbiota transplantation on Satiety and energy metabolis ... 14-05-2025

- Expected prolonged compromised immunity (due to recent cytotoxic chemotherapy or HIV infection with a CD4 count < 240)

- Treatable underlying cause of anorexia/underweight

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	20-12-2016
Enrollment:	24
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	09-01-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

4 - Effect of Intestinal microbiota transplantation on Satiety and energy metabolis ... 14-05-2025

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6181
NTR-old	NTR6336
Other	METC : 2016_180

Study results