

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24821

Bron

Nationaal Trial Register

Verkorte titel

INSTANT trial

Aandoening

anorexia nervosa

Ondersteuning

Primaire sponsor: amc

Overige ondersteuning: amc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

the effect of FMT on different microbiota composition in relation to weight, appetite/satiety (fMRI/questionnaires) and Nutrient Drink Test (incl plasma hormones)

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

baseline ,6 and 12 weeks

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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
- Expected prolonged compromised immunity (due to recent cytotoxic chemotherapy or HIV infection with a CD4 count < 240)
- Treatable underlying cause of anorexia/underweight

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	20-12-2016
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	09-01-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten