

The immune system and microbial tone in relation to NAFLD/NASH before and after BARIatric surgery in the morbidly obese in Amsterdam; the BARIA cohort study.

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It is increasingly recognized that the immune system is a major player in this obesity related disease and the switch from benign to malignant (insulin resistance and DM2) obesity is associated with changes in the immune system. In this regard,...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22589

Bron

Nationaal Trial Register

Verkorte titel

BARIA

Aandoening

obesity
nafld-nash
bariatric surgery

Ondersteuning

Primaire sponsor: amc

Overige ondersteuning: amc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To identify microbial, immunological and metabolic markers associated with weightloss after bariatric surgery. To this end, we will collect before, during surgery and after 2 years follow up.

Toelichting onderzoek

Doel van het onderzoek

It is increasingly recognized that the immune system is a major player in this obesity related disease and the switch from benign to malign (insulin resistance and DM2) obesity is associated with changes in the immune system . In this regard, animal studies have suggested that the intestinal microbiome is thought to play a major role in driving these immunological and metabolites changes. However, at this moment it is unknown whether and to what extend intestinal microbiota and immunological tone can predict metabolic response (improvement in insulin sensitivity and weightloss) upon bariatric surgery. Increased understanding of the pathophysiological mechanism as well as their relationship to metabolic disturbances are thought to be of crucial importance to discover new diagnostic and therapeutical targets in obesity associated insulin resistance and NAFLD/NASH. Moreover, this study will identify the underlying pathophysiological mechanisms in subjects that will have NAFLD/NASH reduction upon the surgery (responders) and those that have no beneficial effect on at all (non-responders). This might help to predict who will benefit from the surgical intervention and in whom this is not effective.

Onderzoeksopzet

0,1,2,12 and 24 months

Onderzoeksproduct en/of interventie

bariatric surgery

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Scheduled for bariatric surgery
- Ability to provide informed consent
- No more than 5% weight loss in 6 months prior to surgery
- No more than 3% weight loss in 1 month prior to surgery

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Known genetic basis for insulin resistance or glucose intolerance
- All medical and psychiatric conditions except for obesity related diseases.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2016
Aantal proefpersonen:	1500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	13-07-2016
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

NTR-new

NTR-old

Ander register

ID

NL5837

NTR5992

: METC 2015_357

Resultaten