Establishing an etiological role of the gut microbiome in the obstetric antiphospholipid syndrome phenotype

Gepubliceerd: 12-04-2019 Laatst bijgewerkt: 13-12-2022

We aim to establish proof-of-concept for an etiological role of the gut microbiome in human oAPS and further hypothesize that this is mediated by increased intestinal permeability.

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

Samenvatting

ID

NL-OMON20326

Bron
NTR

Verkorte titel
ROMAS

Aandoening

Obstetric antiphospholipid syndrome

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Amsterdam Reproduction and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the composite of a broad panel of APS pathophysiology-related blood

biomarkers. These biomarkers are regarded to collectively reflect the oAPS phenotype.

Toelichting onderzoek

Achtergrond van het onderzoek

The ROMAS study aims to establish proof-of-concept for an etiological role of the gut microbiome in human obstetric antiphospholipid syndrome. The study has a pretest-posttest design in which all subjects undergo a 7 day course of oral vancomycin. The primary study outcome is the composite of a broad panel of APS pathophysiology-related blood biomarkers.

Doel van het onderzoek

We aim to establish proof-of-concept for an etiological role of the gut microbiome in human oAPS and further hypothesize that this is mediated by increased intestinal permeability.

Onderzoeksopzet

Day -8, 0, 8, 42

Onderzoeksproduct en/of interventie

All subjects will undergo a 7 day treatment course of oral vancomycin, 500mg 4 times daily, a standard antibiotic.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Obstetric APS diagnosed by Sydney criteria:
1. A history of one or more of the following forms of pregnancy morbidity
(a) One or more unexplained deaths of a morphologically normal fetus at or beyond the 10th week of gestation, with normal fetal morphology documented by ultrasound or by direct examination of the fetus, or
(b) One or more premature births of a morphologically normal neonate before the 34th week of gestation because of: (i) eclampsia or severe pre-eclampsia defined according to standard definitions, or (ii) recognized features of placental insufficiency–,or
(c) Three or more unexplained consecutive spontaneous abortions before the 10th week of gestation, with maternal anatomic or hormonal abnormalities and paternal and maternal chromosomal causes excluded.
2. A history of one or more of the following laboratory criteria
a Lupus anticoagulant (LA) present in plasma, on two or more occasions at least 12 weeks apart, detected according to the guidelines of the International Society on Thrombosis and Haemostasis (Scientific Subcommittee on LAs/phospholipid-dependent antibodies).
b. Anticardiolipin (aCL) antibody of IgG and/or IgM isotype in serum or plasma, present in medium or high titer (i.e. >40 GPL or MPL, or >the 99th percentile), on two or more occasions, at least 12 weeks apart, measured by a standardized ELISA.
c. Anti-b2glycoprotein-I antibody of IgG and/or IgM isotype in serum or plasma (in titer >the 99th percentile), present on two or more occasions, at least 12 weeks apart, measured by a standardized ELISA, according to recommended procedures.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age below 18 years
- Current use of antibiotics
- History of gastro-enteritis in the past month
- History of inflammatory bowel disease
- Planned change in the following medication during the study period (either start, stop or dose change): platelet aggregation inhibitors, oral anticoagulants, heparins, hormonal therapy.
- Current pregnancy or pregnancy in the past 6 weeks
- Arterial or venous thrombosis in the past month
- Allergy to vancomycin

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2019
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	12-04-2019
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	NL7662
Ander register	METC Academic Medical Center Amsterdam : METC2018_288

Resultaten