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

No registrations found.

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

Summary

ID

NL-OMON20326

Source
NTR

Brief title
ROMAS

Health condition

Obstetric antiphospholipid syndrome

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: Amsterdam Reproduction and Development

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Gut permeability measured by lactulose/mannitol test.
Reduction in antiphospholipid antibodiy titers
Subgroup analysis of severe phenotype patients, based on clinical manifestations and antibody profiles

Study description

Background summary

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.

Study objective

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.

Study design

Day -8, 0, 8, 42

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2019
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	12-04-2019
Application type:	First submission

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
NTR-new	NL7662
Other	METC Academic Medical Center Amsterdam : METC2018_288

Study results