Recurrent miscarriages: Causes, treatment and consequences.

Gepubliceerd: 18-10-2011 Laatst bijgewerkt: 13-12-2022

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20356

Bron
NTR

Verkorte titel
Abortion

Aandoening

-recurrent miscarriages -trombophilia -antiphospholipid syndrome

Ondersteuning

Primaire sponsor: LUMC (Leidsch University Mediccal Center)
Overige ondersteuning: -Ministery of OC&W
-Donation NVLE (Nationale vereniging voor lupus, sclerodermie en MCTD)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pregnancy outcome.

Toelichting onderzoek

Achtergrond van het onderzoek

With 1 to 2% of the couples suffering from recurrent miscarriages, prevention would be of undisputable benefit for couples who suffer from recurrent miscarriages on a medical as well as psychological point of view. Understanding mechanisms triggering the maternal immune system in more detail, especially at the maternal-fetal interface, could help to elucidate mechanism behind recurrent miscarriages. An inadequate peripheral maternal immune response against paternal antigens may lead to improper implantation and rejection of the embryo. Both HLA genes and cytokines have been studied extensively in women with recurrent miscarriages. So far no study has focussed on the specific immune response and cytokine production by maternal PMBCs to paternal or umbilical cord cells in couples with recurrent miscarriage. The outcome of these functional studies will be related to HLA analysis of both partners and the newborn. Hopefully these results will give us new insights and possibilities for development of various treatments.

Doel van het onderzoek

The fetus is protected from maternal immune responses through various mechanisms such as lack of expression of classical HLA class I and class II molecules, inhibitory T cell, costimulatory molecules, NK cells, complement regulatory proteins by trophoblasts, and by local maternal regulatory T cells.

We hypothesize that an imbalance between immunomodulatory and effector cells and as a consequence an inadequate cytokine production could be responsible for recurrent miscarriage. This study will include couples with recurrent miscarriages. A prospective study will be performed during the following pregnancy by taking peripheral blood samples, which will be stimulated with paternal, third party (unrelated PBMCs) and, if available cord blood cells expressing HLA-antigens, and monitored for cell proliferation, cytokine production, antibodies and complement activation to determine the difference between ongoing pregnancies and miscarriages.

Onderzoeksopzet

01-12-2011: Start recruiting couples at miscarriage clinic;

01-03-2012: Start first labexperiments;
01-01-2013: Start analyzing results;

01-01-2014: Finishing study.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

PO Box 9600
K.W.M. Bloemenkamp
Department of Obstetrics
Leiden University Medical Centre
Leiden K-6-P; room 35
Leiden 2300 RC
The Netherlands
+31 (0)71 5263360

Wetenschappelijk

PO Box 9600
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The Netherlands
+31 (0)71 5263360

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. > two subsequently miscarriages;

2. Maternal age < 40.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Parental chromosomal abnormalities;

2. Uterus anomalies;

3. Cervical insufficiency;

4. Untreated thyroid disease;

5. Patient mentally or legally incapacity;

6. Any history of/ or recent alcohol or drug abuse;

7. Poor balance or treatment of diabetes mellitus;

8. ART (assisted reproductive technology) pregnancies.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2011
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL2960
NTR-old	NTR3107
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A