Immunology in diabetic pregnancy.

Gepubliceerd: 01-02-2010 Laatst bijgewerkt: 15-05-2024

The immune response of diabetic pregnancies is altered in comparison to healthy pregnant women.

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

Samenvatting

ID

NL-OMON23378

Bron
Nationaal Trial Register

Aandoening

Immunological changes in diabetic pregnancy.

Ondersteuning

Primaire sponsor: University Medical Centre Groningen
Overige ondersteuning: University Medical Centre Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

In case of pregnancy, the peripheral immune response will be determined by taking venous blood samples (10 ml heparinised and 10 ml EDTA) in the third trimester of pregnancy. In case of non-pregnant women, the blood samples will be taken in the follicular phase of the ovarian cycle.

Local immune response: All placentas will be collected after delivery if approval has been obtained and biopsies will be taken in situ of the decidua. Thereby, tissue biopsies will be obtained from the placental bed from the uterus after delivery of the placenta during

caesarean delivery.

Toelichting onderzoek

Achtergrond van het onderzoek

Maternal en foetal complications are still much more present in diabetic pregnancies (in both DM1 and DM2) than in normal pregnancies, despite stringent metabolic control in recent years. This suggests that other mechanisms are involved in the development of diabetes induced pregnancy complications. This hypothesis is subject of the present study. One important mechanism may be the changed immune response, since the immune response in both DM1 and DM2 has been changed.
In DM1 the (auto)immune response is shifted towards a Th¬1-type response. This may not always be compatible with pregnancy, since for a normal pregnancy the normal immune response has to shift to a Th2 type immune response. Next to it, it is important that the numbers of Tregs are increased during pregnancy. These immunological changes of pregnancy have been shown to be necessary to accommodate the semi-allogenic fetus. Deviations from these adaptations are associated with pre-eclampsia, pre-term delivery and/or abortion. So, adequate and strict regulation of immune responses is essential for a normal pregnancy also.

In case of DM2, a low grade general inflammatory response is often observed. The presence of a low level of inflammation in DM2 patients may interfere with pregnancy, since pregnancy itself is also associated with activation of the inflammatory system. Further activation of the inflammatory response during normal pregnancy may result in pregnancy complications, like pre-eclampsia.
Based on mentioned above, we hypothesize that the peripheral and local immune responses in DM1 and DM2 patients are different compared to healthy controls. Consequently, we hypothesize that the changes in immune responses in diabetic pregnancy are associated with the increased numbers of complications during diabetic pregnancies.

Doel van het onderzoek

The immune response of diabetic pregnancies is altered in comparison to healthy pregnant women.

Onderzoeksopzet

Visit 1: information and screening;

Visit 2: Informed consent;

Visit 3: Obtaining blood samples;

Visit 4: Delivery of placenta (in the pregnant groups) and in case of delivery by section caesara tissue biopsies of the placental bed will be obtained.

Onderzoeksproduct en/of interventie

None.

Contactpersonen

Publiek

B. Groen
[default]
The Netherlands
+31 (0)6 10475964

Wetenschappelijk

B. Groen
[default]
The Netherlands
+31 (0)6 10475964

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Group 1: Pregnant women with DM1 >18 en <40 yrs;

Group 2: Pregnant women with DM2 >18 en <40 yrs;

Group 3: Healthy pregnant women >18 en <40 yrs;

Group 4: Non-pregnant women with DM1 >18 and <40 yrs;

Group 5: Non-pregnant women with DM2 >18 and <40 yrs;

Group 6: Healthy non-pregnant women >18 en <40 yrs.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Group 1,2:

1. HbA1c >7,5% after 30 weeks of gestation;

2. Renal failure (serum creatinine >120 µmol/L);

3. Active treatment for auto-immune disease, except substitution therapy for primary hypothyroidism with TBII <1.

Group 3:

1. Gestational diabetes mellitus;

2. Intrauterine growth restriction (defined as foetal weight <10th percentile for gestational age);

3. >2 times of miscarriage (defined as loss of pregnancy during the first 23 weeks of gestation);

4. All other maternal and foetal complications;

5. Known active disease.

Group 4, 5:

1. HbA1c >7,5%;

2. Renal failure (serum creatinine >120 µmol/L);

3. Active treatment for auto-immune disease, except substitution therapy for primary hypothyroidism with TBII <1.

Group 6:

1. Known active disease, except substitution therapy for primary hypothyroidism with TBII <1.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Controle: Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2010
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36546
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2078
NTR-old	NTR2195
CCMO	NL30779.042.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36546

Resultaten

Samenvatting resultaten
N/A