Immunology in diabetic pregnancy.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23378

Source
NTR

Health condition

Immunological changes in diabetic pregnancy.

Sponsors and support

Primary sponsor: University Medical Centre Groningen
Source(s) of monetary or material Support: University Medical Centre Groningen

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To determine the maternal and foetal outcome of diabetic pregnancies in comparison with healthy controls in association with the local and peripheral immune response.

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

None.

Contacts

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

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2010
Enrollment:	120
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 36546
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A