SAF in diabetic pregnancies.

No registrations found.

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

Summary

ID

NL-OMON23319

Source
NTR

Health condition

Diabetes Mellitus
Pregnancy
Advanced Glycation Endproducts

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

To determine the accumulation of AGEs in the skin and serum of pregnant women with DM1, DM2 or GDM, in comparison to healthy pregnant women and non-pregnant women with DM1 or DM2. The accumulation of soft tissue AGEs will be measured by the skin autofluorescence reader and sAGES will be measured in maternal serum.

Secondary outcome

Secondary Objective(s):

1. To asses the inflammatory response by measurement of inflammation markers in maternal serum in pregnant women with DM1, DM2 or GDM. This response will be measured twice, namely firstly in the third trimester and secondly 6-12 weeks after delivery;

2. To asses the relation between skin autofluorescence (SAF) and presence or development of impaired glucose tolerance (IGT) or DM after pregnancy, as assessed by OGTT 6-12 weeks after delivery. Furthermore, the relation between SAF and maternal, fetal and neonatal complications will be assessed.

Study description

Background summary

Maternal en foetal complications are still much more present in diabetic pregnancies (in DM1, DM2 and GDM) 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 increased accumulation of Advanced Glycation Products (AGEs) in long-lived tissues, since the accumulation of AGEs is increased in patient with DM1, DM2 or GDM. This hypothesis is subject of the present study.

AGEs are formed when a reducing sugar, such as glucose, react nonenzymatically with free amino groups on polypeptides or lipids, resulting in formation of reversible early glycation end products, so called Amadori products. Further molecular rearrangements result in the formation of virtually irreversible AGEs. Formation of AGEs is a normal physiological process and tissue concentrations of AGE-modified proteins increase slowly with aging. However, during oxidative and/or glycemic stress, AGEs can be formed more rapidly.

Tissue AGE levels can be assessed noninvasively by the autofluorescence reader (AFR) and serum AGEs can be assessed in maternal serum.

Our aim is to assess skin autofluorescence (SAF) of the lower arm using the AFR and sAGEs in pregnant women who are suffering DM1, DM2 or GDM and to investigate the association between increased AGEs and maternal and fetal complications of diabetic pregnancies. We hypothesize that the accumulation of AGEs will be increased in diabetic pregnancies.

Study objective

The accumulation of, in both serum and tissue AGEs, will be increased in diabetic pregnancies.

Study design

Visit 1: Information and screening;

Visit 2: Informed consent;

Visit 3: Obtaining blood sample and measurement of AGEs accumulation;

Visit 4: Measurement AGEs accumulation;

Visit 5: Meaurement AGEs accumulation;

Visit 6: Obtaining blood sample and measurement of AGEs accumulation (postpartum in case of preganancy).

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Pregnant women with known DM1, DM2, GDM in the age range of 18-40 years. Pregnant women with DM1, DM2 and GDM can only be included when the glucose levels are established in the following range:

HbA1c <8%, if possible measured during last menstrual cycle, last outpatient visit before pregnancy if within period < 4 months or at first visit after positive pregnancy test.

Controls will be healthy pregnant women and non-pregnant women with DM1 or DM2 in the age range of 18-40 years.

Exclusion criteria

Pregnant women with DM1 or DM2:

1. HbA1c >8%;

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

3. Fitzpatrick skin type VI (negroid skin colour), or skin reflectance <6% or local skin abnormalities of the volar side of the lower arms;

4. Recent (< 3 months) serious (requiring hospital admission) infection or cardiovascular event.

Pregnant women with GDM:

1. HbA1c >7% after 20-24 weeks of gestation;

2. Treatment of GDM with diet only;

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

4. Fitzpatrick skin type VI (negroid skin colour), or skin reflectance <6% or local skin abnormalities of the volar side of the lower arms;

5. Recent (< 3 months) serious (requiring hospital admission) infection or cardiovascular event.

Healthy pregnant women:

1. Known active disease;

2. Fitzpatrick skin type VI (negroid skin colour), or skin reflectance <6% or local skin abnormalities of the volar side of the lower arms;

3. Recent (< 3 months) serious (requiring hospital admission) infection or cardiovascular event.

Non-pregnant women with DM1 or DM2:

1. HbA1c >8%;

2. Pregnancy;

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

4. Fitzpatrick skin type VI (negroid skin colour), or skin reflectance <6% or local skin abnormalities of the volar side of the lower arms;

5. Recent (< 3 months) serious (requiring hospital admission) infection or cardiovascular event.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2010
Enrollment:	180
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 34029
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2230
NTR-old	NTR2356
CCMO	NL32041.042.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34029

Study results

Summary results
N/A