SAF in diabetic pregnancies.

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

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

Samenvatting

ID

NL-OMON23319

Bron
NTR

Aandoening

Diabetes Mellitus
Pregnancy
Advanced Glycation Endproducts

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2010
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34029
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A