

Skin Autofluorescence in Gestational Diabetes Mellitus, Compared to Normoglycaemic Gestation

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To investigate whether SAF is elevated in GDM versus non-diabetic pregnancy To investigate whether SAF levels change during the course of normal and GDM pregnancy To investigate if SAF is related to other parameters of hyperglycemia (HbA1c, self...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON34889

Source

ToetsingOnline

Brief title

Skin autofluorescence in gestational diabetes mellitus

Condition

- Diabetic complications
- Maternal complications of pregnancy

Synonym

gestational diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: advanced glycation end products, gestational diabetes, skin autofluorescence

Outcome measures

Primary outcome

SAF level of GDM women compared to non-diabetic pregnant women

Secondary outcome

laboratory assessments: glucose, HbA1c, fructosamine

Study description

Background summary

AGEs can be measured by skin autofluorescence (SAF) and are known to accumulate in diabetes. Moreover the level of SAF predicts macro- and microvascular complications. Since SAF is an indicator of the degree of derangement of the glucose homeostasis, it is well possible that SAF will be elevated in gestational diabetes. It is unknown whether SAF indeed accumulates in gestational diabetes.

Study objective

To investigate whether SAF is elevated in GDM versus non-diabetic pregnancy
To investigate whether SAF levels change during the course of normal and GDM pregnancy
To investigate if SAF is related to other parameters of hyperglycemia (HbA1c, self-monitored blood glucose)

Study design

observational

Study burden and risks

The SAF measurement is a non-invasive procedure, without any risks or side-effects.

The current individual patient does not benefit from participation but with positive results, SAF measurement will contribute to improvement in the care

for patients with GDM.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Pregnant patients (non-diabetic or GDM)
- Written informed consent
- Knowledge of Dutch
- Planned for a screening challenge test (50 gr)

Exclusion criteria

- renal failure (GFR < 30 ml/min)
- Negroid skin type
- skin reflectance < 6% (the AGE-reader will automatically give an alarm when reflection is too low for the measurement to be reliable, these patients will be excluded)
- pre-eclampsia at inclusion
- Recent (< 6 months) serious infection or infarction or hospital admission/ or clinical condition judged by the investigator as interfering with skin autofluorescence measurement
- GDM not confirmed by positive OGTT
- Control (non-diabetic) not confirmed by negative challenge test

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2010
Enrollment:	52
Type:	Actual

Ethics review

Approved WMO	
Date:	01-02-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL29806.041.09