

# Is the Level of Skin Autofluorescence (SAF) Related to Complications in Pregnant Patients with Diabetes Mellitus?

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To evaluate whether a higher SAF level is related to a higher incidence of macrosomia  
To evaluate if a higher SAF level is related to a higher incidence of other maternal, fetal or neonatal complications  
To evaluate if SAF level is related to a...

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

## Summary

### ID

NL-OMON34626

### Source

ToetsingOnline

### Brief title

Skin Autofluorescence in Pregnant Patients with Diabetes Mellitus

### Condition

- Diabetic complications
- Pregnancy, labour, delivery and postpartum conditions

### Synonym

diabetes mellitus

### 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, diabetes mellitus, skin autofluorescence

## Outcome measures

### Primary outcome

SAF level

### Secondary outcome

complications

necessity of insulin

type 2 diabetes after diagnosis

glucose values at OGTT

## 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 level is related to complications in pregnant patients with diabetes.

### Study objective

To evaluate whether a higher SAF level is related to a higher incidence of macrosomia

To evaluate if a higher SAF level is related to a higher incidence of other maternal, fetal or neonatal complications

To evaluate if SAF level is related to a higher necessity of insulin treatment during pregnancy in GDM patients only

To evaluate if SAF level is related to a higher development of type 2 diabetes

during the first year after delivery in GDM patients only

## Study design

Observational

## Study burden and risks

The SAF measurement is a non-invasive procedure, without any risks or side-effects. Measurements coincide with usual outpatient visits. Only in GDM an extra visit is needed 1 year after delivery to measure glucose and SAF again.

The current individual patient does not benefit from participation but with positive results, SAF measurement will contribute to improvement in the care for pregnancy complicated by diabetes.

## Contacts

### Public

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### Scientific

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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 with diabetes (GDM or pre-existent diabetes mellitus) or patients with one abnormal value at OGTT
- Written informed consent
- Knowledge of Dutch

## 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

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 09-03-2010

Enrollment: 300

Type: Actual

## Ethics review

Approved WMO

Date: 24-02-2010

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 21-05-2010

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 30-06-2010

Application type: Amendment

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	NL30990.041.09