# Inflammatory aspects of glucose in hyperlipidemia and diabetes

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To get more insight in the inflammatory processes induced by glucose in heallthy volunteers and patients with insulin dependent T2DM and hyperlipidemia.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Glucose metabolism disorders (incl diabetes mellitus) |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON31196

**Source**
ToetsingOnline

**Brief title**
INFORM

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym**
Diabetes mellitus, Hyperlipidemia

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Sint Franciscus Gasthuis
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Atherosclerosis, Glucose, Hyperlipidemia, Inflammation

## Outcome measures

### Primary outcome

In this study, inflammatory aspects (leukocyte activation and complement

system) in different groups of subjects will be investigated during an OGTT.

### Secondary outcome

Not applicable.

# Study description

### Background summary

Cardiovascular disease (CVD) is number one killer in the Netherlands. Insulin resistance and dyslipideima are the main causes of CVD. Recently, we have shown that there is an acute leukocyte activation after an oral glucose tolerance test (OGTT) in patients with newly-diagnosed diabets mellitus type 2 (T2DM). Leukocyte activation is an important and obligatory aspect in the process of atherosclerosis. Complement system is another important inflammatory component in atherosclerosis, which becomes activated in the postprandial phase.
In this study, we will investigate both inflammatory systems in healthy volunteers and patients with T2DM on insulin therapy and hyperlipidemia (both familial hyperlipidemia (FH) and familial combined hyperlipidemia (FCH)) during an OGTT.

### Study objective

To get more insight in the inflammatory processes induced by glucose in heallthy volunteers and patients with insulin dependent T2DM and hyperlipidemia.

### Study design

Healthy subjects between 45 and 65 years will be recruited by advertisement in Sint Franciscus Gasthuis Rotterdam (SFG). Patients with T2DM on insulin therapy and hyperlipidemia will be recruited from the out patient clinics of the internal and vascular medicine of SFG en type 2 (via dr. Castro Cabezas and dr.

Alipour). The patients will receive a letter, in which the study is explained. One week after this letter the patients will be called by dr. alipour and asked whether they want to participate. The healthy volunteers and the patients who have agreed to participate will be invited for a meeting. In this meeting written informed will be explained and obtained. Furthermore, medical and family history, list of medication and some (anthropometric) measurements (weight, length, waist circumference and bloodpressure) will be obtained.
20 healthy volunteers, 20 subjects with T2DM on insulin therapy and 40 hyperlipidemic subjects (20 with hypercholesterolemia and 20 with hypercholesterolemia and hypertriglyceridemia) will be included. The subjects will be scheduled to undergo the OGTT. Therefore, they will vist the laboratory (while fasting for 10 hours). before (t=0 minuts) and after (t=60 en t=120 minuts) ingesting a standardised glucose, blood will be obtained in order to do the measurements.

**Study burden and risks**

Except for the risks of peripheral intravenous blood sampling (hematoma) and hyperglycemia in T2DM patients on insulin therapy (who are used to deal with this condition), there will be no additional risks.

# 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

·Provide written informed consent
·Aged 45-65 years
·BMI < 35 kg/m2

## Exclusion criteria

·Emotionally and intellectually not capable to decide about participation in the study and the consequences of participation. Subjects who are not able to understand the patient information
·Diabetes mellitus treated with oral antidiabetic medicine
.Type 1 diabetes mellitus
·peripheral artery and/or coronary disease
.Untreated hypertension
·Alcohol use > 2 units/day
·Aberrations in kidney, liver and thyroid function
·Use of any experimental medication within 6 months of the study
·The use of immunosuppressive drugs

# Study design

## Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 25-10-2007 |
| Enrollment: | 80 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 04-09-2007 |
| Application type: | First submission |
| Review commission: | TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam) |

## 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 | NL17100.101.07 |