

# Ex vivo LPS stimulation in healthy and compromised subjects

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To determine whether a difference in resilience of inflammatory tone between healthy and prediabetic males can be identified with whole blood ex vivo LPS stimulation.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Glucose metabolism disorders (incl diabetes mellitus)
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON36944

### Source

ToetsingOnline

### Brief title

Ex vivo LPS stimulation study

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

### Synonym

diabetes, overweight

### Research involving

Human

### Sponsors and support

**Primary sponsor:** TNO

**Source(s) of monetary or material Support:** TNO

## Intervention

**Keyword:** ex vivo, inflammation, lipopolysaccharide, prediabetes

## Outcome measures

### Primary outcome

After ex vivo LPS stimulation of blood samples, cytokine parameters including TNF- $\alpha$ , IL-6, IL-1 $\beta$ , IL-10, IL-8, IFN-gamma, IL-12 and IL-1RA will be measured.

### Secondary outcome

Not applicable.

## Study description

### Background summary

It is hypothesized that ex vivo LPS stimulation of whole blood will induce a measurable inflammatory cytokine response in a healthy population that is different from a response of the prediabetic overweight population. Possibly certain dietary intervention can be applied to influence on the cytokine parameters to improve the condition of health compromised group.

### Study objective

To determine whether a difference in resilience of inflammatory tone between healthy and prediabetic males can be identified with whole blood ex vivo LPS stimulation.

### Study design

This is a single centre, observational, case-control study with whole blood ex vivo LPS challenge. No intervention will be administered.

### Study burden and risks

As there is no investigational product for intervention, clinically relevant side effects will not be expected.

The medical screening may result in unexpected findings.

## Contacts

### Public

TNO

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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

- Males
- aged 35 to 45 years, on study day 1
- Healthy volunteers are defined based on medical history evaluation, physical examination, results of the pre-study laboratory tests and a health and lifestyle questionnaire, with following criteria: HbA1c  $\leq$  5.5% (37 mmol/mol) or fasting glucose  $\geq$  3.4 and  $\leq$  5.6 mmol/L ; further the waist circumference  $<$  94 cm; and body fat percentage between 8-24.9%.
- The prediabetics with overweight meet the following criteria: HbA1c in the range of 6.0 - 6.5% (42 - 48mmol/mol) Or fasting glucose in the range of 6.1-6.9 mmol/L; further the waist circumference  $\geq$  102 cm; and body fat percentage  $\geq$  25 %.

## Exclusion criteria

- Having a history of medical or surgical events that may significantly affect the study outcome, including any psychiatric history, and metabolic or endocrine disease, or any gastro-intestinal disorder or inflammatory diseases;
- Use of any medication 14 days before day 01; use of paracetamol 7 days before day 01.
- Currently smoking or stopped smoking less than 6 months ago
- Alcohol consumption  $\geq$  21 units per week
- Exercise more than five hours per week
- Use of dietary supplements (e.g. fish oil capsules, polyphenols and vitamins)

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Will not start
Start date (anticipated):	15-07-2012
Enrollment:	36
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	11-07-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	

Date: 23-08-2012  
Application type: Amendment  
Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## 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	NL40983.058.12