

# The Santiago-study

## An observational study on the vascular and metabolic effects of a pilgrimage.

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In this study the effects of a two-week moderately intense-intense physical activity on vascular function, glucose-metabolism, lipid-metabolism and adipose tissue function will be analyzed.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Glucose metabolism disorders (incl diabetes mellitus)
<b>Study type</b>	Observational invasive

### Summary

#### ID

NL-OMON33351

#### Source

ToetsingOnline

#### Brief title

The Santiago Study

#### Condition

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

#### Synonym

decreased vascular function, endothelial dysfunction

#### Research involving

Human

#### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Kostenplaats vasculaire geneeskunde

## Intervention

**Keyword:** Endothelial function, Insulin sensitivity, Physical exercise, Pilgrimage

## Outcome measures

### Primary outcome

Differences in FMD measurement results between the exercise group and control group directly before and after the walking-route. ( $\Delta\text{FMD}$ - $\Delta\text{FMD}$ )

### Secondary outcome

1. Differences in EndoPAT measurement results between the exercise group and control group directly before and after the walking-route. ( $\Delta\text{EndoPAT}$ - $\Delta\text{EndoPAT}$ )

2. Differences in PWV measurement results between the exercise group and control group directly before and after the walking-route. ( $\Delta\text{PWV}$ - $\Delta\text{PWV}$ )

3. Differences in insulin resistance, glucose concentrations, lipid concentrations and adipokine concentrations between the exercise group and control group directly before and after the walking-route

## Study description

### Background summary

Rationale:

A sedentary lifestyle has been linked to increased cardiovascular morbidity and mortality. A trend towards decreased physical activity in the past decades has led to an increased prevalence of obesity and obesity-related complications such as cardiovascular disease, diabetes and cancer. It has been shown in different populations that exercise training programs lead to an improvement of the cardiovascular risk profile by enhancing insulin sensitivity, altering the lipid profile and reducing blood pressure. Endothelial dysfunction appears

early in the process of atherosclerosis and has been associated with cardiovascular disease. Endothelial function may improve after intervening in cardiovascular risk factors. Likewise, exercise has been shown to improve endothelial function in several previous studies.

In this study the effects of a two-week moderately intense-intense physical activity on vascular function, glucose-metabolism, lipid-metabolism and adipose tissue function will be analyzed in healthy participants of a Santiago pilgrimage compared to controls.

### **Study objective**

In this study the effects of a two-week moderately intense-intense physical activity on vascular function, glucose-metabolism, lipid-metabolism and adipose tissue function will be analyzed.

### **Study design**

Observational cohort study, with a control group.

### **Study burden and risks**

The Santiago-study is an observational study. Non-invasive techniques will be used to assess endothelial function, vascular stiffness, central blood pressure and heart rate variability.

Invasive procedures are limited to vena punctures and finger pricks to obtain blood samples (total amount of  $\pm$  85 ml of blood during the study per study subject).

4 Visits at the study site will be planned, which will last for approximately 1.5 hours each.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Inclusion criteria

1. Male or female subjects, 40-70 years of age
2. Voluntary participation in the Santiago de Compostela pilgrimage (only applicable for the exercise group)
3. Written and signed informed consent

### **Exclusion criteria**

1. A history of diabetes mellitus or use of glucose-lowering medication
2. A recent history (within the last year) of alcohol or drug abuse or dependence
3. Changes in blood pressure lowering medication in the previous month and/or insufficiently controlled hypertension (systolic blood pressure >170 mmHg)
4. Usage of any lipid-lowering medication
5. A history of mental instability or major psychiatric illness not adequately controlled and stable on pharmacotherapy
6. A current (advanced) malignancy and/or current treatment for malignancy
7. A history of significant aortic coarctation
8. Significant deformity of fingers of either hand prohibiting use of the same digit on both hands for EndoPAT-measurement
9. A history of upper extremity thrombosis

## **Study design**

## Design

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

**Primary purpose:** Basic science

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	08-05-2009
Enrollment:	60
Type:	Actual

## Ethics review

Approved WMO	
Date:	21-04-2009
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**

CCMO

**ID**

NL26889.041.09