

# Screening of Hindustani people for risk factors of cardiovascular disease

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|                              |   |
|------------------------------|---|
| <b>Ethical review</b>        | Approved WMO                              |
| <b>Status</b>                | Recruitment stopped                       |
| <b>Health condition type</b> | Cardiac disorders, signs and symptoms NEC |
| <b>Study type</b>            | Observational non invasive                |

## Summary

### ID

NL-OMON40911

### Source

ToetsingOnline

### Brief title

SHIVA

### Condition

- Cardiac disorders, signs and symptoms NEC
- Glucose metabolism disorders (incl diabetes mellitus)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

### Synonym

arteriosclerotic vascular disease, atherosclerosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** LUMC;MCH

## Intervention

**Keyword:** Cholesterol, Diabetes, Prevention, Risk factors

## Outcome measures

### Primary outcome

Asymptomatic young Hindustanis have an increased CV risk profile, which demands vigilance and early risk factor modification to prevent long-term CV events.

### Secondary outcome

NVT

## Study description

### Background summary

Asian Indian migrants in the Western world are highly susceptible for ischaemic heart disease (IHD). Until now, most IHD risk studies were performed in first and second generation Asian Indian expatriates. For optimal prevention, knowledge of the cardiovascular risk profile of younger generations is crucial.

### Study objective

The primary objective of this study is to assess the CV risk profile of Hindustanis without known diabetes mellitus (DM), hypertension, dyslipidemia or CV disease and evaluate the 10-year CV risk according to the Framingham risk score. Secondary objectives are to assess the value of screening in this healthy subpopulation and to find unrecognised patients who should be treated according to the Dutch guidelines.

### Study design

On a mass cultural event in 2004, 2100 asymptomatic Hindustanis, age >18 yr, were recruited. Ten percent of these population had a disease which needed an treatment according the NHG-guidelines. In 2014 at a mass cultural event (Milan Festival) the follow up study will continue to evaluate the incidencence of any cardiovascular event or treatment (medication) of diabetes, hypertension or hypercholesterolaemia. There will also be a screening of new participants (asymptomatic hindustanis >18 years) for risk factors of cardiovascular

diseases.

## **Study burden and risks**

NVT

## **Contacts**

### **Public**

Leids Universitair Medisch Centrum

Albinusdreef 2  
Leiden 2300 RC  
NL

### **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**

Asymptomatic Hindustanis, age > 18 yr

## Exclusion criteria

Hypertension, hypercholesterolaemia, diabetes or treatment (medication) for any of these.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-07-2014

Enrollment: 2500

Type: Actual

## Ethics review

Approved WMO

Date: 24-09-2014

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

## 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     | NL49460.058.14 |