

IJsselstein Screening for Central Obesity to detect metabolic syndrome

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1) To determine the prevalence of MetS in the patient population of the MMIJ in IJsselstein aged 20 to 70 years
2) To assess the effectiveness of population screening for MetS by general practitioners in a medium-size city in the Netherlands

Ethical review

Approved WMO

Status

Recruitment stopped

Health condition type

Glucose metabolism disorders (incl diabetes mellitus)

Study type

Observational invasive

Summary

ID

NL-OMON30055

Source

ToetsingOnline

Brief title

IJSCO

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders
- Vascular hypertensive disorders

Synonym

insulin resistance syndrome, metabolic syndrome

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Julius Research

Source(s) of monetary or material Support: industrie, Merck Sharpe & Dohme (MSD)

Intervention

Keyword: metabolic syndrome, population screening, primary care, waist circumference

Outcome measures

Primary outcome

The MetS prevalence (according to NCEP/ATP III criteria) in the patient population of the MMIJ in IJsselstein aged 20 to 70 years.

Secondary outcome

The secondary outcome is the effectiveness of population screening for MetS by general practitioners in a medium-size city in the Netherlands, determined by determinants such as response rate, sensitivity and specificity of the screening, costs per detected MetS patient and the percentage of patients treated by their GP after 6 months for any diagnosed risk factor.

Study description

Background summary

The Health Council of the Netherlands concluded in 2004 that a general population screening for type 2 diabetes is not recommended, but suggested a screening focussed on prevention of cardiovascular diseases to be performed in a high-risk group of obese subjects. Such a screening is the IJSCO study, where we aim to detect metabolic syndrome patients. The concurrence of cardiovascular risk factors in the metabolic syndrome is associated with an increased risk of cardiovascular diseases.

Study objective

- 1) To determine the prevalence of MetS in the patient population of the MMIJ in IJsselstein aged 20 to 70 years
- 2) To assess the effectiveness of population screening for MetS by general practitioners in a medium-size city in the Netherlands

Study design

Eligible patients (except patients known with diabetes (type 1 or 2), hypertension, dyslipidaemia, or metabolic syndrome) will be invited to measure their waist circumference with a provided tape measure and record this on a stamped addressed card. Patients with a waist circumference above the cut-off value of 88 cm (for women) or 102 cm (for men) will be invited to attend a visit to investigate the presence of the other cardiovascular risk factors of the metabolic syndrome. Investigations will include physical examination, blood and urine collection and a questionnaire.

For patients known with diabetes (type 1 or 2), hypertension, dyslipidaemia, or metabolic syndrome the data will be extracted from their medical dossiers.

Study burden and risks

The burden associated with the study for the patient is minimal: one visit (20 minutes) and one venapuncture. The only risk is possibly a small hematoma at the venapuncture site. The possible benefit for the patient is the reduction of cardiovascular risk by treatment of the detected cardiovascular risk factors.

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

Men and women aged 20 up to 70 years

Exclusion criteria

Pregnancy

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 09-10-2006

Enrollment: 15000

Type: Actual

Ethics review

Approved WMO

Date: 08-08-2006

Application type: First submission

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	24-10-2006
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	14-11-2006
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	NL11657.041.06