IJsselstein Study of Central Obesity

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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-OMON33262

Source
ToetsingOnline

Brief title
IJSCO-2

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: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: het Investigator Initiated Studies Program van MSD,Merck Sharpe & Dohme (MSD)

Intervention

Keyword: Central obesity, Metabolic syndrome, Primary care

Outcome measures

Primary outcome

The main endpoint is the remission of the metabolic syndrome in the 473 people with screen-detected metabolic syndrome. Metabolic syndrome will be determined according to NCEP ATP III-criteria.

Secondary outcome

- Changes in the separate components of the metabolic syndrome: waist circumference, blood pressure, HDL cholesterol, triglycerides and fasting glucose
- Changes in lifestyle, with regard to smoking, alcohol use and physical activity
- The development of type 2 diabetes or cardiovascular disease since the screening
- Cardiovascular medications that were prescribed after the screening
- Illness perception with regard to obesity

Study description

Background summary

In 2004 the Health Council of the Netherlands suggested targeted screening for various cardiovascular risk factors in a high-risk group of obese subjects, instead of a general population-based screening for type 2 diabetes.
Such a screening was the IJSCO study (IJsselstein Screening for Central Obesity to detect metabolic syndrome), which aimed to detect metabolic syndrome patients. All patients of the 'Medische Maatschap IJsselstein' aged 20-70 years

who were not known with diabetes, hypertension or dyslipidemia were asked to measure their waist circumference. 1721 people with a self-measured increased waist circumference were invited for further research. In 473 the metabolic syndrome was detected. Halve of the detected cases was between 30 and 50 years old. In this agegroup, people visit their general practitioner less often. This makes screening even more relevant. The metabolic syndrome prevalence among all people aged 20-70 years in IJsselstein was 15.5%.

Screening participants were asked to contact their general practice three weeks after the screening for their results. They were treated according to the guidelines of the Dutch College of General Practitioners.

Study objective

Following the participants three more years will enable us to get a better overview of the consequences of the screening with regard to treatment, health, lifestyle modifications and illness perception with regard to obesity.

Primary Objective:
• To assess the remission of the metabolic syndrome following standard care about three years after screening in people with screen-detected metabolic syndrome, and to assess which determinants at the time of diagnosis predict remission of screen-detected metabolic syndrome within three years following usual care.

Secondary Objectives:
• To assess how the health status developed with regard to waist circumference, body mass index (BMI), blood pressure, fasting glucose and lipid spectrum in patients with central obesity that were screened for the metabolic syndrome;
• To assess how many patients developed diabetes mellitus or cardiovascular disease
• To assess which cardiovascular medications were prescribed to patients with screen-detected metabolic syndrome;
• To assess how lifestyle changed over a three years follow-up period in patients with central obesity with and without the metabolic syndrome;
• To identify those patients who are likely not to adhere to suggested preventive measures with regard to their lifestyle after they were diagnosed with the metabolic syndrome;
• To assess illness perception with regard to obesity in patients with central obesity with and without the metabolic syndrome.

Study design

Observational study.
All screening participants that were detected with the metabolic syndrome will be invited for further research. As a control group, we will also invite a

random sample of the participants with central obesity that did not meet the metabolic syndrome criteria. Investigations will include a short physical examination, blood collection and a questionnaire.

Study burden and risks

The burden associated with the study for the patient is minimal: one visit 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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Central obesity measured during the screening for the metabolic syndrome in 2006/2007

Exclusion criteria

Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2009
Enrollment:	673
Type:	Actual

Ethics review

Approved WMO Date:	28-10-2009
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	ID
CCMO	NL28515.041.09