Population based randomized controlled trial of screening for type 2 diabetes mellitus in high-risk subjects.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23901

Source
NTR

Brief title
N/A

Health condition

Type 2 Diabetes Mellitus

Sponsors and support

Primary sponsor: Primary Sponsor: Erasmus MC, Department of Public Health. Secondary Sponsors: GGD (Municipal Health Service) Zuid Holland Zuid and GGD Rotterdam en omsreken.
Source(s) of monetary or material Support: Zon-Mw, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

1. Cardiovascular morbidity and mortality based on the first occurrence of a non-fatal cardiovascular event (coronary heart disease, cerebrovascular accident, and death from any other disease of the circulatory system);
2. All cause mortality.

Secondary outcome

1. Prevalence of unknown type 2 diabetes detected by screening;
2. Screening performance: attendance, referral and detection rates, and test characteristics;
3. Contamination rates;
4. Change over time in the level of blood parameters: glucose, lipids, glycated haemoglobin and blood pressure in diabetic subjects;
5. Change/improvement in the cardiovascular risk profile after screen-detected diabetes and comparisons with control arm;
6. Modifications in lifestyle (diet, physical activity level, smoking) in both type 2 diabetes cases and those with IFG;
7. Cost aspects.

Study description

Background summary

The aim of this study is to establish whether systematic screening for type 2 diabetes mellitus in high-risk obese subjects can significantly reduce the diabetes-related cardiovascular morbidity and mortality among diabetic patients by at least 25%, resulting in a 5% reduction of these endpoints within the entire overweight/obese population. The study will be a population-based RCT in a high-risk group and has a total duration of 10 years. In the first year, feasibility of the project will be assessed in 20% of the intended sample size. Inclusion criteria are age (40-74 years), self-reported waist circumference (>80cm for women and > 94cm for men), long-term follow-up feasible, i.e. no presence of other chronic diseases that makes 5-year survival unlikely and no previous diagnosis of type 1 or type 2 diabetes. After identification of the personal data from municipal registries, 450.000 people will receive an invitation letter, information brochure, questionnaire, tape-measure and consent form. We aim at including 62.000 men and women, to be equally randomized over two study arms. The screening arm will be invited for a fasting plasma glucose (FPG) measurement. Blood lipids and blood pressure in a subset of individuals will additionally be measured to evaluate the ‘overlap’ between these risk factors in the obese population. Participants with ‘diabetes’ or ‘impaired fasting glucose’ will be referred to their GP for further diagnostics and treatment. The control arm will not be invited for a FPG. Both groups will receive written information about beneficial effects of a healthy life style. The primary endpoint is based on the first occurrence, within the follow-up period after randomization, of a fatal or non-fatal cardiovascular event.

Study objective

Systematic screening for type 2 diabetes in high-risk obese subjects, identified from the general population, can significantly reduce the diabetes-related cardiovascular morbidity and mortality by at least 25% compared with not offering a screening program.

Intervention

Subjects will be randomized into a screening group and a control group. All subjects who have been allocated to the screening group will be invited for screening which comprises a fasting plasma glucose test (FPG). Additionally, serum triglycerides, total-cholesterol and HDL-cholesterol and LDL-cholesterol will be measured. LDL-cholesterol will be calculated using the Friedewald equation. Those subjects with diabetes (FPG of 7.0 mmol/L or higher) or impaired fasting glucose (FPG between 5.7-6.9 mol/L) will be referred to the general practitioner for further diagnostic testing and/or treatment for type 2 diabetes according to NHG-guidelines. Individuals with normal FPG (5.6 mmol/L or lower) will be invited for re-screening after 4 years. All subjects in both groups will receive written lifestyle intervention advice.

Contacts

Public
Erasmus Medical Center, Department of Public Health,
P.O. Box 1738
H.J. Koning, de
Rotterdam 3000 DR
The Netherlands
+31 (0)10 4087723
Scientific
Erasmus Medical Center, Department of Public Health,
P.O. Box 1738
H.J. Koning, de
Rotterdam 3000 DR
The Netherlands
+31 (0)10 4087723

Eligibility criteria

Inclusion criteria

1. Age (40 to 74 years inclusive);
2. Waist circumference;
3. Accounting for ethnicity;

4. Women: 80 cm or higher, men: 94 cm or higher;
5. Long-term follow-up feasible;
6. No presence of other chronic diseases that makes 5-year survival unlikely.

Exclusion criteria

Pre-existing type 1 or 2 diabetes.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-05-2006
Enrollment:	62000
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-05-2006
Application type:	First submission

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
NTR-new	NL632
NTR-old	NTR692
Other	: N/A
ISRCTN	ISRCTN75983009

Study results

Summary results
N/A