ISRCTN75983009 https://doi.org/10.1186/ISRCTN75983009

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

Submission date 19/07/2006	**Recruitment status** No longer recruiting
Registration date 19/07/2006	**Overall study status** Completed
Last Edited 27/10/2014	**Condition category** Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes Mellitus type 2 (DM type II)

Interventions
Subjects will be randomized into a screening group or a control group. All subjects who have been allocated to the screening group will be invited for screening which comprises a fasting plasma glucose (FPG) test. Additionally, serum triglycerides, total-cholesterol, high-density lipoprotein (HDL) cholesterol and low-density lipoprotein (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 Dutch College of General Practitioners (NHG) guidelines. Individuals with normal FPG (5.6 mmol/l or lower) will be invited for re-screening after four years. All subjects in both groups will receive written lifestyle intervention advice.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
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 measures
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 or 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 impaired fasting glucose (IFG)
7. Cost aspects

Overall study start date
15/05/2006

Completion date
15/05/2016

Eligibility

Key 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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

62000

Key exclusion criteria
Pre-existing type 1 or 2 diabetes

Date of first enrolment
15/05/2006

Date of final enrolment
15/05/2016

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3000 DR

Sponsor information

Organisation
Erasmus Medical Center, Department of Public Health (The Netherlands)

Sponsor details
P.O. Box 2040
Rotterdam
Netherlands
3000 CA

Sponsor type
University/education

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/08/2012		Yes	No
Results article	results	01/02/2014		Yes	No