

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

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 |