DIAbetes-PREvention Trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38088

Source
ToetsingOnline

Brief title
DiaPreT

Condition

- Other condition
- Coronary artery disorders

Synonym
Heart problems, pre-diabetics

Health condition

pre-diabetici

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Isala klinieken (zorgvernieuwing)

Intervention

Keyword: Cardiac rehabilitation, Coronary artery disease (PCI or CABG in stable CAD or post STEMI and post non-STEMI), Pre-diabetes

Outcome measures

Primary outcome

The reduction in HbA1c at one year in patients with coronary artery disease

(PCI or CABG in stable CAD, or post STEMI and post non-STEMI patients)

Secondary outcome

- hsCRP

- LDL cholesterol

- MACE at one year FUP

- Exercise capacity

Study description

Background summary

Not only the incidence of diabetes is increasing, but also the incidence of pre-diabetes, defined as an impaired glucose tolerance test or impaired fasting glucose. A recent study showed that in China almost 140 million people have pre-diabetes, more than 15% of the total adult population. The incidence depends on the definition of pre-diabetes. Other investigators have defined pre-diabetes based on the HbA1c level. The rise in prevalence of pre-diabetes is associated with the increase in obesity and physical inactivity. Intense exercise has been shown to reduce the HbA1c level in patients with diabetes. In addition, oral anti-diabetic agents have been shown to be effective in patients with pre-diabetes.

Study objective

The primary objective of this randomized trial is to reduce the HbA1c levels by

10% through exercise training with or without oral anti-diabetic medication in patients with coronary artery disease (PCI or CABG in stable CAD, or post STEMI and post non-STEMI patients) that have pre-diabetes.

Study design

Patients who meet the inclusion criteria and non of the exclusion criteria will be randomized in a 1:1:1 fashion to an exercise training programme, an exercise training programme in combination with oral anti-diabetic medication (Metformine) during 1 year or regular treatment (6 weeks).

Intervention

Patients participating in this trial will be followed-up at 6 and 12 months after admission. Data regarding patient*s history and current health status at follow-up will be collected and entered into the database by the investigator.

Study burden and risks

All subjects will require follow-up visits to our hospital at 6 and 12 month (± 30 days) after the index myocardial infarction. Subjects will undergo screening of cardio vascular complications or death, hospitalisation and concomitant medication.
The study medication for patients randomized to the treatment group: *Exercise training and Oral anti-diabetic medication*, consists oral Metformine.

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

Inclusion criteria ;• • Patients admitted with coronairy artery disease (PCI or CABG in stable CAD, or post STEMI and post non-STEMI) (inclusion within 2 month after admission) ;• Age >= 18 years ;• Elevated HbA1c levels (HbA1c > 5.8% or > 40 mmol/mol) on admission ;• Access to a computer with internet connection;• Written informed consent

Exclusion criteria

Exclusion criteria ;• Known diabetics, with or without anti-diabetic medication ;• Contra-indications for Metformine use as stated in the medication registration;• Life Expectancy <1 yr ;• Physical limitations/restrictions for participation in exercise programme or exercise testing ;• Fasting plasma glucose >= 7.0 mmol/l or HbA1c >= 53

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2012
Enrollment:	78
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Metformine hydrochloride
Generic name:	Metformine hydrochloride
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	31-05-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	12-10-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	08-05-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	10-05-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	20-12-2012

Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	11-02-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21355
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2011-002469-39-NL
CCMO	NL37115.075.11
OMON	NL-OMON21355