Supplemental oxygen to improve the efficiency of exercise training therapy in type 2 diabetes patients.

No registrations found.

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

Summary

ID

NL-OMON21976

Source
NTR

Brief title
HOEX (Hyperoxic Exercise)

Health condition

Diabetes mellitus type 2

Sponsors and support

Primary sponsor: Erasmus MC
P.O.Box 2040, NL-3000 CA Rotterdam
phone: +31 10 703 18 87 / 31 80 (secr)
Source(s) of monetary or material Support: Diabetes Fonds
Stationsplein 139
3818 LE Amersfoort
033 -4622055

Intervention

Outcome measures

Primary outcome

Main study parameters/endpoints: The main study parameter and end-point is the relative improvement in whole-body insulin sensitivity.

Secondary outcome

Secondary end-points are relative improvements in vascular function parameters using forearm plethysmography, cardiovascular fitness, systemic blood pressure, body composition, lipid metabolism and glycemic control.

Study description

Background summary

Rationale:
Type 2 diabetes patients frequently suffer from physical deconditioning and vascular disease. Although the exact mechanisms are unclear, microvascular changes and endothelial dysfunction appear to inhibit the oxygen transport and uptake in peripheral skeletal muscle of type 2 diabetes patients. Hyperoxic-training has been shown a safe intervention to increase exercise capacity and energy expenditure and is now routinely used for athletes (‘live-high, train-low’) and COPD patients. Furthermore, in COPD patients normalisation of oxygen saturation improves insulin sensivity.

Objective:
This research project aims to investigate (1) whether hyperoxic interval training improves insulin resistance, endothelial dysfunction, cardiovascular fitness, lipid metabolism and glycemic control in the treatment of deconditioned non-insulin dependent type 2 diabetes patients and (2) the pathophysiological role of endothelial dysfunction and insulin. resistance on the adaptive response to exercise.

Study design:
double-blind placebo controlled intervention study.
Study population:
36 deconditioned non-insulin dependent type 2 diabetes patients.

Intervention:
After inclusion, subjects will be randomised and blinded to 16 weeks of progressive 30-45 min cycle ergometer interval training, applied 3 times a week while breathing either hyperoxic (100%O2, 4-8 L/min) or normoxic (21%O2-79%N2, 4-8L/min) humidified air (=placebo) through a nasal tube.

Main study parameters/endpoints:
The main study parameter and end-point is the relative improvement in whole-body insulin sensitivity. Secondary end-points are relative improvements in vascular function parameters using forearm plethysmography, cardiovascular fitness, systemic blood pressure, body composition, lipid metabolism and glycemic control.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Before inclusion subjects will undergo a physical examination and X-ECG to exclude cardiovascular disease and assess cardiorespiratory status. A subgroup of 12 subjects will undergo a submaximal exercise test while obtaining arteriovenous blood samples to optimize oxygen flow during exercise. All 36 participating subjects will be asked to attend a total of 48 supervised exercise sessions of 45 min. To minimize the risk for a hypoglycemic event during the first 2 weeks of the exercise intervention, capillary blood glucose will be measured following exercise. If necessary medication will be adjusted. Independent of oxygen concentration in the air mixture, patients are expected to improve their physical fitness and metabolic control. Beside the direct therapeutic effects, both interventions are expected to improve general health and well-being.
Although unlikely, in theory hyperoxic exercise training might worsen diabetes related retinopathy. Therefore, an experienced ophthalmologist will monitor and stage diabetic retinopathy before and after the 16 weeks training program. Dual energy x-ray absorptiometry will be used to assess changes in body composition. Frequently sampled intravenous and forearm venous occlusion plethysmography following intrabrachial infusions of methacholine and sodium nitroprusside will be applied. Participating subjects will visit the clinical research unit 9 times over a 5 months time period, equivalent to a 22 hours time load. Over a period of 20 weeks multiple arterialised and venous blood samples (equivalent to 258 cc) will be drawn through an intravenous/arterial catheter.

Study objective

This research project hypothesises that hyperoxic interval training improves whole body insulin resistance, endothelial dysfunction, cardiovascular fitness, lipid metabolism and

glycemic control in the treatment of deconditioned non-insulin dependent type 2 diabetes patients.

Study design

1. Baseline measurements aftrer inclusion;

2. Endpoint measurements after 16 weeks.

Intervention

After inclusion, 12 patients will participate in the dosefinding study (substudy 1). The remaining 36 subjects will be randomised and blinded to 16 weeks of progressive 30-45 min cycle ergometer interval training, applied 3 times a week while breathing either hyperoxic (100%O2, 4-8 L/min) or normoxic (21%O2-79%N2, 4-8L/min) humidified air (=placebo) through a nasal tube (substudy 2).

Contacts

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Eligibility criteria

Inclusion criteria

1. Type 2 diabetes according to WHO criteria for over 2 years;

2. VO2peak 60-90% of age-predicted value as measured on a cycle-ergometer;

3. Motivated and willlling/able to travel 3 times a week to Erasmus MC and participate in a supervised exercise intervention program.

Exclusion criteria

1. Use of ß-blocker therapy;

2. Exogenous insulin therapy (for substudy 2 only);

3. Use of oral anti-coagulans therapy/low molecular heparin;

4. Decompensatio cordis, angina pectoris, myocardial infarction or positive signs of cardiac ischaemia on the ECG during the incremental exercise test;

5. Orthopaedic impairments that would limit participation in the training program;

6. Co-morbidity such as renal failure or >grade III retinopathy or previous diabetic foot ulcer;

7. Cerebro-vascular disease (CVA), neurological diseases or deficits;

8. A history of glaucoma or high intraocular pressure will be contraindication for dilated fundus reflex photography).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-09-2009
Enrollment:	36
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-09-2009
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	NL1898
NTR-old	NTR2014
Other	METC Erasmus MC : 2009-125
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A