Diabetes and vascular complications: normoxia versus hypoxia

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Our aim is to compare the effect of 8-week exercise training and exercise training under hypoxia on vascular adaptations in function and structure, but also metabolic control (insulin resistance)

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON35263

Source
ToetsingOnline

Brief title
DM-Hypoxia

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes mellitus type 2

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diabetes mellitus, hypoxia, physical fitness

Outcome measures

Primary outcome

1) Endothelial function (measured as the flow-mediated dilation (FMD))

2) Vascular structure (measured as the intima-media thickness (IMT))

3) Metabolic function (measured as insulin resistance)

Secondary outcome

N/A

Study description

Background summary

Type 2 diabetes mellitus (T2DM) represents a major health problem in the Western society. Aging, increasing prevalence of obesity and decreasing physical activity levels will even further increase the prevalence of T2DM. In addition to the presence of insulin resistance, the primary pathologic consequence of T2DM involves vascular impairment. Consequently, T2DM is an independent cardiovascular risk factor and relates to micro- and macrovascular complications. Endothelial dysfunction is believed to importantly contribute to the vascular complications in diabetes.
Several previous studies, including from our laboratory, have demonstrated that aerobic exercise training is an effective therapeutic strategy to improve insulin resistance, but also reverses endothelial dysfunction. Recent studies have adopted novel exercise training strategies to further improve the beneficial effects of exercise training. For example, aerobic exercise training combined with mild hypoxia (~2,000 m altitude) is suggested to enhance weight loss, decrease leptin levels (with suppression of appetite), increases activity of glycolytic enzymes, elevate the number of mitochondria and glucose transporter GLUT-4 and produce peripheral vasodilation and arteriogenesis. Consequently, one may hypothesise that exercise training under hypoxia may have a superior effect to improve insulin resistance and improve endothelial function compared to traditional exercise training in DMT2.

Study objective

Our aim is to compare the effect of 8-week exercise training and exercise training under hypoxia on vascular adaptations in function and structure, but also metabolic control (insulin resistance)

Study design

Intervention study

Study burden and risks

Patients with type 2 diabetes will undergo blood withdrawal (for measures of metabolic control) and non-invasive measurements of vascular function and structure before and after the 8-week intervention. The Department of Physiology has a long track-record using the proposed techniques to examine the vasculature and metabolic control in healthy subjects as well as in patient groups (e.g. spinal cord injury, older subjects, type 1 and 2 diabetes mellitus). These tests involve the repetitive inflation of blood pressure cuffs and application of the non-invasive echo-Doppler technique. We have never had problems regarding these non-invasive tests nor complaints from our test subjects.
The Department of Physiology has a long and strong history of performing exercise training studies in healthy volunteers (children, adolescents, middle-aged and older subjects) as well as various patient groups (including diabetes mellitus type 1 and 2). Hypoxic exercise training will be performed in a specifically designed room with air mixture of 16.5% O2 (b-Cat mobile high altitude chamber, b-Cat B.V., Tiel, the Netherlands). This type of exercise training is safe as it is comparable to performing exercise at ~2,000 m altitude. Therefore, this type of exercise is comparable to the type of exercise that a large part of the world*s population is being exposed to (those who live at >2,000 m altitude). This type of training is not associated with any health risk. Normoxic and hypoxic exercise training will take place under supervision of an experienced researcher. Taken together, our study involves non-invasive measures and makes use of novel and safe exercise training strategies that are believed to have a strong and potent health benefit for DMT2.

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

Diagnosed with type 2 diabetes mellitus at least 2 years ago

Exclusion criteria

- Cardiovascular disease
- Hypercholesterolemia and/or subjects on cholesterol-lowering drugs
- Hypertension (>160 mmHg systolic and/or >90 mmHg diastolic pressure) and/or subjects on antihypertensive drugs
- Smoking
- Type I diabetes mellitus
- Older than 65 years
- Subjects with vascular complications due to type 2 diabetes mellitus (e.g. diabetic foot ulcer)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-05-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	10-04-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL39040.091.11

Study results

Date completed:	13-12-2012
Actual enrolment:	20