# **Optimalization of exercise therapy in type 2 diabtes patients.**

Gepubliceerd: 04-01-2013 Laatst bijgewerkt: 18-08-2022

Primary hypothesis: Based on the aforementioned study results we hypothesize that a single exercise bout performed under hypoxic conditions will reduce the 24-hour post-exercise quantity of hyperglycemic episodes more efficiently in comparison with...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

# Samenvatting

## ID

NL-OMON29246

Bron NTR

#### Aandoening

Diabetes, insulin resistance, hyperglycemia.

## Ondersteuning

**Primaire sponsor:** Erasmus University **Overige ondersteuning:** Erasmus University

## **Onderzoeksproduct en/of interventie**

## Uitkomstmaten

#### Primaire uitkomstmaten

Measurement of the 24-hour glycemic profile in response to acute sub-maximal hypoxic and hyperoxic exercise in order to determine its effectiveness and select the most efficient method in reducing post-exercise hyperglycemia prevalence in comparison with normoxic conditions.

# **Toelichting onderzoek**

#### Achtergrond van het onderzoek

DM2 is considered a dangerously growing pandemic problem. Physical exercise has a prominent role in the treatment of type 2 diabetes mellitus (DM2). This study aims to optimize exercise intervention programs in aspect of a more efficient reduction of hyperglycemia prevalence in response to a single bout of exercise in various oxygen conditions. The study results, regarding a hemodynamic response as well, will contribute to select the most effective oxygen conditions inducing short-term beneficial effects in glycemic profile. Furthermore, obtained results will be implemented in planning tailor-made exercise interventions aiming for a greater improvement in longitudinal glycemic control.

It has been shown that acute hypoxic exercise is known to promote glucose uptake in skeletal muscle via a contraction stimulated pathway, independent of insulin action. Methods which have been used in order to accurately measure glucose disposal in the liver and muscle require a laboratory environment and do not represent daily life circumstances. Alternatively, in the previous research subcutaneous continuous glucose monitoring system (CGMS) has been shown as sensitive equipment to accurately monitor the acute effects of normoxic exercise on the level of hyperglycemia in normoxic daily living conditions. In accordance, the first aim of the proposed study is to investigate whether a single bout of hypoxic exercise is more efficient in reducing 24-hour hyperglycemia prevalence in comparison with normoxic conditions.

Despite proven efficacy of exercise in lowering hyperglycemia, presence of diabetes complications and impaired exercise tolerance warrants new strategies to facilitate higher exercise intensities during exercise intervention programs in order to improve their overall efficiency. It has been shown in COPD patients that perceived exertion is lower during hyperoxic exercise. In accordance, more efficient reduction of post-exercise hyperglycemia in comparison with normoxic conditions may be induced by better-tolerated as well as an increased caloric expenditure.

As such, in the second part of this study our aim is to investigate whether a better-tolerated and more intensive single bout of exercise will reduce the 24-hour hyperglycemia prevalence more efficiently in comparison with normoxic exertion.

The third aim of the present study is to improve our understanding of the cardiovascular, respiratory and microcirculatory mechanisms that may mediate the blood glucose lowering effects of either hypoxic or hyperoxic exercise in DM2 patients. Therefore, noninvasive measurements of peripheral (muscle blood flow) and central (cardiac output) hemodynamic parameters are expected to provide us with new insight about the net physiological limitations/possibilities in sub-maximal exercise performance and glucoregulation in DM2 patients. Also, new insights about both the acute effects of hypoxic and hyperoxic exercise are required before deciding on a medium to long-term exercise intervention study in either

hypoxic or hyperoxic conditions.

The study group will consist of 12 DM2 non-insulin treated patients (age 40-65 yr, BMI 25-35 kg/m2). Patients will undergo 1 maximal and 3 steady-state sub-maximal tests in various oxygen conditions on separate days. Additionally, subjects will be monitored by noninvasive equipment for hemodynamic and cardio-respiratory measurements. During the experimental trial blood glucose profiles of subjects will be monitored by portable CGMS devices for 2 days.

#### Doel van het onderzoek

#### Primary hypothesis:

Based on the aforementioned study results we hypothesize that a single exercise bout performed under hypoxic conditions will reduce the 24-hour post-exercise quantity of hyperglycemic episodes more efficiently in comparison with normoxic conditions.

Considering the above mentioned research on lower perceived exertion during hyperoxic exercise, we hypothesize that better tolerated, more intensive acute hyperoxic exertion will further reduce the 24-hour post-exercise hyperglycemia prevalence more efficiently in comparison with normoxic exercise.

#### Onderzoeksopzet

01-03-2012: Start;

- 01-04-2012: MEC submission and Clinical Trial registration;
- 01-06-2012: Logistics/study setup;
- 01-08-2012: Inclusion of the last subjects and measurements;
- 01-11-2012: Accomplishing the trial;
- 01-01-2013: Reports and submission of a manuscript in a peer-reviewed journal;
- 01-03-2013: The end of the study and final reports.

#### **Onderzoeksproduct en/of interventie**

Acute submaximal exercise bouts in hypoxic and hyperoxic conditions.

# Contactpersonen

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## Wetenschappelijk

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# **Deelname eisen**

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 1. DM2 >3 months;
- 2. Age: 40-65 years;
- 3. BMI between 27 and 35 kg/m2;
- 4. Formal permission to participate in the study by signing an informed consent form.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Cardiovascular disease: Objective heart failure (ejection fraction <35%), electrocardiographically diagnosed cardiac ischemia or symptomatic peripheral vascular

disease diagnosed by Doppler ultrasound investigation;

2. Serious orthopedic of neurological conditions precluding an exercise test.

# Onderzoeksopzet

## Opzet

Туре:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

## Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-03-2012
Aantal proefpersonen:	12
Туре:	Verwachte startdatum

# **Ethische beoordeling**

Positief advies	
Datum:	04-01-2013
Soort:	Eerste indiening

# Registraties

# **Opgevolgd door onderstaande (mogelijk meer actuele) registratie**

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

# In overige registers

Register	ID
NTR-new	NL3547
NTR-old	NTR3777
Ander register	METC Erasmus MC : 2012-128
ISRCTN	ISRCTN wordt niet meer aangevraagd.

# Resultaten

#### Samenvatting resultaten N/A