

Should type two diabetes patients exercise at high or low intensity levels for the improvement of glycaemic control?

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
11/02/2008	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
21/04/2008	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
09/01/2013	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Effects of long-term exercise training intensity on glycaemic control in type two diabetes patients

Acronym

ITIIRO trial

Study objectives

Low- and moderate-to-high intensity exercise training are equally effective for improving glycaemic control in obese, type two diabetes patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Research Ethics Committee of the Virga Jesse Hospital, Hasselt (Belgium) on the 25th November 2004 (ref: 04.38/cardio04.05).

Study design

Randomised two armed clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type two diabetes mellitus

Interventions

All patients were subjected to eight weeks of endurance exercise training, three days each week, one subgroup at high intensity while the other at low intensity. Pharmacological treatment and caloric intake were not changed. All patients were followed for eight weeks.

Other sponsors:

1. Vrije Universiteit Brussel (Belgium)

Pleinlaan 2

Brussels

B-3500

Belgium

Website: <http://www.vub.ac.be>

2. Virga Jesse Hospital (Belgium)

Stadomvaart 11

Hasselt

B-3500

Belgium

Email: rego@virgajesse.be

Website: <http://www.virgajesse.be>

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Body composition
2. Blood plasma parameters
3. Exercise performance capacity

All measurements were made at 0 and 8 weeks of exercise training.

Key secondary outcome(s)

1. Skeletal muscle biopsy parameters
2. Physical activity level
3. Food intake

All measurements were made at 0 and 8 weeks of exercise training.

Completion date

31/12/2007

Eligibility

Key inclusion criteria

1. Obese, male, type two diabetes patients (at least one year diagnosed with disease)
2. Have not participated in physical activity programs or caloric intake restriction programs for at least two years ahead of study
3. Aged 40 - 75 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

1. Exogenous insulin use
2. Cardiac/renal/pulmonary diseases

Date of first enrolment

10/12/2003

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Belgium

Netherlands

Study participating centre

Universiteitssingel 50

Maastricht

Netherlands

6229 ER

Sponsor information

Organisation

University Maastricht (UM) (The Netherlands)

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

University/education

Funder Name

Maastricht University (Netherlands)

Alternative Name(s)

Maastricht University, UM

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Netherlands

Funder Name

The Heart Centre of Hasselt (Hartcentrum Hasselt) (Netherlands)

Results and Publications

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?
<u>Results article</u>	results	01/09/2009		Yes	No
<u>Results article</u>	results	01/11/2012		Yes	No