ISRCTN32206301 https://doi.org/10.1186/ISRCTN32206301

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

Submission date
11/02/2008

Recruitment status
No longer recruiting

Registration date
21/04/2008

Overall study status
Completed

Last Edited
09/01/2013

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Luc van Loon

Contact details
Universiteitssingel 50
Maastricht
Netherlands
6229 ER
+31 (0)43 388 1397
l.vanloon@hb.unimaas.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

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

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

Overall study start date
10/12/2003

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

Age group
Adult

Sex
Male

Target number of participants
50

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)

Sponsor details
Postbus 616
Maastricht
Netherlands
6200 MD

Sponsor type
University/education

Website
http://www.unimaas.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/09/2009		Yes	No

Results article	results	01/11/2012	Yes	No