ISRCTN14894739 https://doi.org/10.1186/ISRCTN14894739

Effect of aerobic exercise with diet on blood sugar control and cardiovascular health of male patients with type 1 and 2 diabetes mellitus

Submission date
27/03/2016

Recruitment status
No longer recruiting

Registration date
05/04/2016

Overall study status
Completed

Last Edited
05/04/2016

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes is a life-long condition where a person is unable to control their blood sugar levels. There are type main types of diabetes. In type 1 diabetes the body is unable to produce a hormone called insulin, which is responsible for breaking down glucose and turning it into energy. In type 2 diabetes the body either does not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). There is a lot of evidence showing that regular exercise and a healthy diet can help control blood sugar, as well as offering other benefits such as improving cardiovascular (heart and blood vessels) health, reducing the risk of heart attack and stroke. The aim of this study is to find out whether aerobic exercise and diet on blood sugar control and cardiovascular health in male patients with type 1 or type 2 diabetes.

Who can participate?
Males with type 1 or type 2 diabetes aged nine years and over.

What does the study involve?
Participants are divided into one of two groups, based on the order that they sign up for the study. Those in the first group (who signed up first) take part in a 12 week course of exercise and dieting. The diet consists of following food recommendations for diabetic patients, namely low calorie intake and avoiding high sugar and saturated fat. The exercise involves 50-minute exercise sessions three times a week, which involves running on a treadmill. Those in the second group continue with their lives as usual for the 12 weeks of the study. At the start of the study and then again after 12 weeks, participants in both groups are weighed and have a blood test to test their blood sugar levels after they have not eaten or drunk anything for 12 hours (fasting).

What are the possible benefits and risks of participating?
Participants may benefit from an improvement in blood sugar control and cardiovascular health. There is a risk that during exercise blood sugar could drop below healthy levels, however this is will be carefully monitored.

Where is the study run from?
1. King Fahd University of Petroleum and Minerals (Saudi Arabia)
2. King Fahd University Hospital (Saudi Arabia)

When is the study starting and how long is it expected to run for?
January 2013 to May 2013

Who is funding the study?
Investigator initiated and funded (Saudi Arabia)

Who is the main contact?
Dr Mohammed Hamdan Hashem Mohammed
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Contact information

Type(s)
Public

Contact name
Dr Mohammed Hamdan Hashem Mohammed

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of aerobic exercise with diet on blood sugar control and cardiovascular health of male patients with type 1 and 2 diabetes mellitus: A parallel group randomized control trial

Study objectives
A 12-week aerobic exercise program combined with a diet will significantly improve the glycemic control and cardiovascular health of the patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Department of Biological and Sport Health Science, Alexandria University, Egypt, 13/05/2012

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
Participants are divided into one of two groups in a 1:1 ratio. The patients who registered first are in the intervention group.

Intervention group: Participants complete a combination of 50-minute exercise sessions done three times a week for 12 weeks (17 February-8 May 2013) and diet. The patients in the control group were asked to continue with their daily activities. The exercise program involves aerobic exercises on treadmills. This involves a 5 minute warm up and cool down before and after the exercise. The exercise intensity was increased progressively: 40-60% in the first four weeks, 60-70% in the second four weeks, and 70-90% in the last four weeks. The increase depended on the ability of the patients. The diet consists of food recommendations for diabetic patients. It provides the amount of calories for the patients to reach and maintain their ideal weight. Each patient has a number of calories to consume, depending on the target weight ideal body weight they need to reach or maintain during and at the end of the program. The patients have the following caloric options: 1200, 1400, 1500 and 1800 calories. The body weight of the patients is measured weekly in order to determine if the patients followed the diet program. Each patient is expected to attain a weekly target body weight if they followed the diet recommendations. The patients are advised to avoid foods with high sugar and saturated fat content.

Control group: Participants continue with their daily activities alone.

Participants are followed up at 12 weeks to have their glycemic control and cardiovascular health assessed.

Intervention Type
Other

Primary outcome measure
Glycemic control is assessed by measuring HbA1c and fasting blood glucose after a 12-hour fast using Dimension® RxL Max® at baseline and 12 weeks

Secondary outcome measures
1. Cardiovascular health is assessed at baseline and 12 weeks:
1.1. Resting heart rate is measured manually at the radial artery (number of beats in 15 seconds was multiplied by four)
1.2. Systolic and diastolic blood pressures are measured using a sphygmomanometer
1.3. Blood lipid profile is measured after a 12-hour fast using Dimension® RxL Max®
2. Body mass is measured using a weighing scale at baseline and 12 weeks
3. Body mass index is calculated using the formula mass/height2 at baseline and 1 weeks

Overall study start date
01/01/2013

Completion date
08/05/2013

Eligibility

Key inclusion criteria
1. Males, aged 9 years and over
2. Diagnosis of type 1 and type 2 diabetes mellitus for more than one year
3. Absence of chronic diseases such as retinopathy, neuropathy, asthma, arthritis, morbid obesity and cardiovascular disease
4. Able to attend study centre

Participant type(s)
Patient

Age group
Mixed

Sex
Male

Target number of participants
60

Key exclusion criteria
1. Aged under 9 years
2. Diabetes diagnosis for less than one year

3. Chronic diseases such as retinopathy, neuropathy, asthma, arthritis, morbid obesity and cardiovascular disease.
4. Those unable to attend the study centre

Date of first enrolment
01/01/2013

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Fahd University of Petroleum and Minerals
Dhahran
Saudi Arabia
31261

Study participating centre
King Fahd University Hospital
Bashar Ibn Burd St
Al Khobar
Saudi Arabia
34445

Sponsor information

Organisation
Alexandria University

Sponsor details
Ethical Committee of the Department of Biological and Sport Health Science
Faculty of Physical Education for Men
Alexandria
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Sponsor type
University/education

ROR
https://ror.org/00mzz1w90

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in refereed journals.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request