

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/04/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/04/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Alexandria University

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21913

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

Egypt

21913

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