

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of continuous aerobic training, high intensity interval training (HIIT) and combined aerobic with resistance training on glycated haemoglobin (HbA1c) in Type 2 Diabetes Mellitus patients with coronary artery disease

Protocol summary

Summary

Introduction: Exercise is well known to be part of the prevention and management of type 2 diabetes mellitus (T2DM) as it helps with blood glucose control.

Cardiovascular complication in diabetes is one of the components for morbidity and mortality in those patients. Objective: The aim of this study is to compare the reduction in glycated hemoglobin (HbA1c) between continuous aerobic training, high intensity interval training and combined aerobic with resistance training in T2DM patients with coronary artery disease (CAD).

Design: This is a randomized clinical trial looking at 3 types of supervised exercise intervention involving T2DM patients with CAD. Settings and conduct: Type 2 diabetes mellitus patients with coronary artery disease is recruited from the endocrine and cardiology clinic University Malaya Medical Centre. Patients Participants: Patients who fulfill the inclusion and exclusion criteria as listed below are recruited: Inclusion criteria for the subjects are patients with type 2 diabetes mellitus with coronary artery disease co-morbidity manifested by one or more of these: -Ischemic Heart Disease, but no current angina -Post angioplasty / stenting or post coronary artery bypass surgery -Stable pharmacological therapy - Chronic Heart Failure New York Association (NYHA I, II and III) in the absence of congestive heart failure at the time of study Patients with the listed criteria are excluded from the study: -Myocardial Infarction, Cardiac arrest, symptomatic or sustained ventricular tachycardia in the previous 6 months -Unstable heart failure, or NYHA Class IV patients -Symptomatic or sustained ventricular tachycardia -Current angina or baseline assessment suggesting unsatisfactory control of heart failure - Current acute musculoskeletal event and/or neurological impairments that adversely affect exercise capacity. - Any other symptoms that prevent the patients from

exercising. Intervention: Subjects are divided into 3 groups using the Peto et al. randomization method. Group 1 is doing continuous aerobic training, Group 2 doing high intensity interval training (HIIT) and Group 3 is doing combined aerobic with resistance training. Patient's assessments are done before and after 12 weeks of exercise intervention. Main outcome measure: To look at the changes in HbA1c after 12 weeks of exercise intervention. Venous blood is also withdrawn to look at the fasting blood glucose and fasting lipid profile. Patient's maximum oxygen consumption (VO₂max) is measured with cycle ergo meter using either Astrand or Naughton protocol. Patient's body composition is also monitored using the InBody370 body impedance analysis machine

General information

Acronym

CADEX Study

IRCT registration information

IRCT registration number: **IRCT2014120820239N1**

Registration date: **2015-01-02, 1393/10/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-02, 1393/10/12

Registrant information

Name

Moriffin Mahpis

Name of organization / entity

University Malaya Medical Centre

Country

Malaysia

Phone

+60379498122

Email address

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Recruitment status

Recruitment complete

Funding source

University Malaya Research Grant UMRG No. RG366-11HTM

Expected recruitment start date

2012-06-01, 1391/03/12

Expected recruitment end date

2013-03-31, 1392/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of continuous aerobic training, high intensity interval training (HIIT) and combined aerobic with resistance training on glycated haemoglobin (HbA1c) in Type 2 Diabetes Mellitus patients with coronary artery disease

Public title

Sugar control following different exercises in diabetic patients with heart disease

Purpose

Supportive

Inclusion/Exclusion criteria

Patients who fulfill the inclusion and exclusion criteria as listed below are recruited: Inclusion criteria for the subjects are patients with type 2 diabetes mellitus with coronary artery disease co-morbidity manifested by one or more of these: -Ischemic Heart Disease, but no current angina -Post angioplasty / stenting or post coronary artery bypass surgery -Stable pharmacological therapy - Chronic Heart Failure New York Association (NYHA I, II and III) in the absence of congestive heart failure at the time of study Patients with the listed criteria are excluded from the study: -Myocardial Infarction, Cardiac arrest, symptomatic or sustained ventricular tachycardia in the previous 6 months -Unstable heart failure, or NYHA Class IV patients -Symptomatic or sustained ventricular tachycardia -Current angina or baseline assessment suggesting unsatisfactory control of heart failure - Current acute musculoskeletal event and/or neurological impairments that adversely affect exercise capacity. - Any other symptoms that prevent the patients from exercising.

Age

From **36 years** old to **74 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This is a randomized prospective trial. Randomization is done using the Peto et al method.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Medical Ethics Committee

Street address

University Malaya Medical Centre

City

Lembah Pantai

Postal code

59100

Approval date

2011-10-19, 1390/07/27

Ethics committee reference number

883.20

Health conditions studied**1****Description of health condition studied**

type 2 diabetes mellitus with coronary artery disease

ICD-10 code

E11

ICD-10 code description

non insulin dependent diabetes mellitus

Primary outcomes**1****Description**

HbA1c (glycated haemoglobin)

Timepoint

12 weeks following end of treatment

Method of measurement

Blood sample laboratory test

Secondary outcomes

1

Description

body composition

Timepoint

12 weeks following end of treatment

Method of measurement

bioelectrical impedance analysis machine

2

Description

lipid profile

Timepoint

12 weeks following end of treatment

Method of measurement

Blood sample laboratory test

3

Description

fasting blood glucose

Timepoint

12 weeks following end of treatment

Method of measurement

Blood sample laboratory test

4

Description

Maximum oxygen consumption (VO₂max)

Timepoint

12 weeks following end of treatment

Method of measurement

cycling ergometer using Astrand or Naughton protocol

Intervention groups

1

Description

Continuous aerobic training: 30 minutes walking on a treadmill and 30 minutes of cycling on an upright bike with moderate intensity (50-70% VO₂max). Total training duration of 60 minutes.

Category

Lifestyle

2

Description

High intensity interval training (HIIT): Subjects will train on cycling ergometer which last for 10 minute duration. They will start with gradual incremental intensity training for 6 minutes (maximum intensity 60-70% VO₂max) then low intensity for another 4 minutes as their warm up session. Then the HIIT session consisted of 10 minutes exercise with every 60 seconds between low intensity and high intensity alternately. The cycle ergometer is set with resistance 40% VO₂max for low intensity and 60-70% VO₂max for high intensity. During the 60 second

high intensity session, patients are to force and encourage to increase their cycle repetition per minute to maximum with the target in achieving Borg score of 17 and above. They were monitored and supervised during the 20 minute session.

Category

Lifestyle

3

Description

Combined aerobic with resistance training: Continuous 30 minutes walking on a treadmill and 30 minutes of cycling on an upright bike at moderate intensity (50-70% VO₂max). Then they have to do resistance training such as chest press, latissimus dorsi pull, leg press, leg extension or leg curl, abdominal muscle crunch and back extension. Total training duration is about 90 minutes

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

University Malaya Medical Centre

Full name of responsible person

Moriffin Mahpis

Street address

Sports Medicine Department

City

Petaling Jaya

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University Malaya Research Grant (UMRG)

Full name of responsible person

Mohd Nahar Azmi B Mohamed (supervisor)

Street address

5th Floor Menara Selatan

City

Petaling Jaya

Grant name

Grant code / Reference number

RG366-11HTM

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University Malaya Research Grant (UMRG)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty