Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 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

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Malaysia

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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

Person responsible for general inquiries

Contact
Name of organization / entity
University Malaya Medical Centre
Full name of responsible person
Moriffin Mahpis
Position
Master of Sports Medicine
Other areas of specialty/work
Street address
5th floor Menara Selatan
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Person responsible for scientific inquiries

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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