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The DIASTOLIC Study

Submission date 25/11/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/11/2015	**Overall study status** Ongoing	
Last Edited 09/08/2019	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Obesity is a medical term used to describe someone who is very overweight. It is generally caused by eating too much and doing too little exercise. Being obese can lead to a number of serious and potentially life-changing medical conditions. Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or their body's cells don't react to insulin as they should do (insulin resistance). Studies have shown that adults who are suffering from T2DM are more vulnerable to developing problems with their heart and blood vessels (cardiovascular disease), although the reasons for this are not fully understood. This project aims to discover exactly how T2DM causes changes in the heart in young people with T2DM. In addition we will attempt to see if the heart's pumping function can be improved either by a weight loss program with a special low calorie diet, or by a structured program of exercise.

Who can participate?
Obese adults who are suffering from T2DM, and obese adults who are in good general health.

What does the study involve?
Participants are randomly allocated to one of three groups. The first group are provided with standard lifestyle advice and contacted weekly to encourage compliance to diet and exercise. The second group are provided with a total meal replacement diet along with health behaviour coaching and relapse prevention through weekly contact with a dietician. The third group attend thrice weekly 60-minute supervised exercise sessions. All participants undergo detailed scans and other tests of the heart's structure and function.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Leicester Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
November 2015 to August 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Emer Brady

Contact information

Type(s)
Public

Contact name
Ms Emer Brady

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02590822

Secondary identifying numbers
19757

Study information

Scientific Title
Diabetes Interventional Assessment of Slimming or Training tO Lessen Inconspicuous Cardiovascular dysfunction (DIASTOLIC)

Study objectives
The aim of this study is to:
1. Discover exactly how type 2 diabetes causes changes in the heart in young people with type 2 diabetes by performing detailed scans and other tests of the heart's structure and function
2. Find out if the heart's pumping function can be improved, either by a weight loss program with a special low calorie diet, or by a structured program of exercise

Ethics approval required
Old ethics approval format

Ethics approval(s)

West Midlands - Coventry & Warwickshire Research Ethics Committee, 01/07/2015, ref: 15/WM/0222

Study design
Randomised; Interventional; Design type: Prevention, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Diabetes; Subtopic: Type 2; Disease: Cardiovascular disease

Interventions
Transthoracic echo, 2 0 20 mins Cardiac physiologists, Cardiovascular BRU, Glenfield

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
Increase in circumferential peak early-diastolic strain rate (PEDSR) rate is measured using cardiovascular magnetic resonance imaging (CMR) at 12 weeks.

Secondary outcome measures
Not provided at time of registration

Overall study start date
05/11/2015

Completion date
31/08/2028

Eligibility

Key inclusion criteria

Diabetic patient inclusion criteria:
1. Aged between 18 and 60 years
2. Capacity to provide informed consent before any trial- related activities
3. Established T2DM for at least 3 months
4. HbA1c = 9% if on triple therapy or = 10% on diet & exercise or monotherapy or dual therapy
5. Current glucose lowering therapy either mono, dual or triple of any combination of metformin, sulphonylurea, DPP-IV inhibitor, GLP-1 therapy or an SGLT2 +/-- diet and exercise
6. Body mass index > 30Kg/m2 (white Europeans) or > 27Kg/m2 (South East Asian or Afro--Caribbean)
7. Diagnosis of T2DM before the age of 50 years of age

Healthy controls inclusion criteria:
1. Aged between 18 and 60 years
2. Capacity to provide informed consent before any trial- related activities
3. Body mass index < 30Kg/m2 (white Europeans) or < 27Kg/m2 (South East Asian or Afro--Caribbean)
4. No cardiovascular symptoms (angina, limiting dyspnoea)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120; Description: phase 1: 100 patients and 20 controls phase 2: 90 patients

Key exclusion criteria
Diabetic patient exclusion criteria:
1. Aged under 18 or over 60
2. HbA1c >10%
3. Diabetes duration >12 years
4. Currently taking more than three glucose lowering therapies
5. Weight-loss of >5kg in the preceding 6 months
6. Stage 4 or 5 chronic kidney disease (eGFR <30ml/min/1.73m2)
7. Current therapy with insulin, thiazolidinediones (or within the preceeding three months), steroids or atypical antipsychotic medication, untreated thyroid disease
8. Known ischaemic heart disease or heart failure
9. Inability to exercise or undertake a TDR
10. Absolute contraindication to CMR
11. Cardiovascular symptoms (angina, limiting dyspnoea).
12. Patients with asthma will be assessed for suitability of adenosine stress. If adenosine is contraindicated (severe asthma) subjects can participate without perfusion assessment
13. Inflammatory condition e.g. connective tissue disorder, rhematoid arthritis.

Healthy controls inclusion criteria:
1. Aged under 18 or over 60
2. Diabetes or impaired glucose tolerance
3. Obesity (BMI >30 (white european) or >27 (Asian or Afro-Caribbean)
4. Severe asthma
5. History of hypertension, or blood pressure in excess of either 160mmHG systolic or 100mmHG diastolic and currently untreated
6. Inflammatory condition e.g. connective tissue disorder, rheumatoid arthritis
7. Congenital heart disease
8. Renal impairment (eGFR <60ml/min/m2)
9. Other conditions that in the opinion of the investigators may limit exercise capacity or be associated with subclinical cardiac dysfunction
10. Competitive athletes

Date of first enrolment
05/11/2015

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
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Sponsor information

Organisation
University of Leicester

Sponsor details
Dept of Health Sciences (General Practice)
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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Other publications	preliminary study	01/07/2018	10/04/2019	Yes	No
Protocol article	protocol	30/03/2019	10/04/2019	Yes	No
HRA research summary			28/06/2023	No	No