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Early detection of cardiovascular dysfunction and health behaviours in the young with type 2 diabetes

Submission date
04/07/2011

Recruitment status
No longer recruiting

Registration date
23/12/2011

Overall study status
Completed

Last Edited
22/08/2016

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes develops when the body does not produce enough insulin to maintain a normal blood sugar (glucose) level, or when the insulin that is being produced does not work properly (insulin resistance). If this happens then blood glucose levels can become high because it is unable to use the glucose for energy. Those with type 2 diabetes are at an increased risk of heart disease, stroke, kidney failure and eyesight problems (diabetic retinopathy). Type 2 diabetes is usually associated with obesity and other risk factors include high blood pressure and a family history of the condition. The number of people with type 2 diabetes is increasing dramatically in the UK. Type 2 diabetes used to be a condition of older people, but more and more young people are showing signs of this disease. In order to develop ways of treating diabetes in the young, it is necessary to understand why it develops and how this affects their health. For this study we plan to collect data on lifestyle, ability to exercise, diet, heart and nerve function to help us start to develop better education and treatment goals in young people with type 2 diabetes. This data will help us to develop an understanding of the impact of type 2 diabetes on the lifestyle of young adults.

Who can participate?
To take part you need to be between 18 and 40 years old and diagnosed with type 2 diabetes, or to be in the control group (without type 2 diabetes) you must have a body mass index (BMI) between 18.5-24.9 kg/m2 or over 29.9 km/m2.

What does the study involve?
If you take part you will go to Loughborough University for your first visit. There you will complete health questionnaires about your diet and any physical activity you do and a clinician will ask you some questions about your lifestyle and understanding of type 2 diabetes. Afterwards, you will have your weight, height, waist and hip circumference and blood pressure measured. Next you will cycle on a stationary bike for about 10 minutes to measure your fitness and give a small blood sample before and after cycling. Your heart rate will be measured when you are cycling.
One week later you will go to Glenfield Hospital where images of your heart will be taken during

a cardiac magnetic resonance imaging (MRI) scan. You will give a blood sample before the scan and a range of measures will be checked including glucose, insulin, vitamin D, cholesterol, thyroid function and measures of inflammation and immune function. A routine electrocardiogram (heart trace) will also be performed before the MRI scan.
Between the two study visits your physical activity will be measured using a meter similar to a pedometer (called an accelerometer) which is worn on your waist band. It records how much activity you do in a day. You will wear this meter for 1 week, during waking hours.

What are the possible benefits and risks of participating?
This study itself will not be of direct benefit to you but it will lead to further research in this area which could improve the treatment of people with type 2 diabetes. However, by taking part you will be provided with information about how much physical activity you perform and how your heart functions using the latest technology. The results of this study will be used to improve future assessment and care for patients like you and it is likely you will have a better understanding of why you may have developed Type 2 diabetes (if you are a patient) and the effects of this disease on your heart function.
Taking part involves minimal risk for you, just the inconvenience of taking the time to participate in the study. MRI scanning and exercise tests are very safe and both will be monitored by a doctor from the research team.
The tests in the study are not designed for clinical diagnosis, but in the unlikely event that we may find an abnormality this will be discussed directly with you. With your permission, we will pass this information to your GP and any relevant specialist(s) with the aim of organising prompt and appropriate investigation and treatment.

Where is the study run from?
The first visit of the study takes place at Loughborough University in the Exercise Laboratory in the Clyde Williams building. The second visit takes place at the Radiology Department at Glenfield Hospital, Leicester.

When is the study starting and how long is it expected to run for?
Patients and control participants have started enrolling for the study from October 2009 until May 2011.

Who is funding the study?
The Medical Research Council.

Who is the main contact?
Dr Emma Wilmot
Emma.Wilmot@uhl-tr.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Emma Wilmot

Contact details
Leicester Royal Infirmary
Infirmary Square

Leicester
United Kingdom
LE1 5WW
-
emma.wilmot@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7506

Study information

Scientific Title
Early detection of cardiovascular dysfunction and health behaviours in the young with type 2 diabetes: an observational study

Study objectives
To characterise health behaviours and beliefs and document early cardiovascular dysfunction in the young with type 2 diabetes (T2DM). This is a pilot study to extensively phenotype young people with T2DM. Biochemical markers and objective measures of metabolic and vascular dysfunction and measures of health behaviours and beliefs will be assessed. These data will be used to design an appropriate lifestyle intervention and early risk reduction and structured education programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Nottinghamshire Research Ethics Committee,13 March 2009, ref: 09/H0407/9

Study design
Non-randomised observational study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Diagnostic

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
Type 2 diabetes

Interventions
Description: 20 young people (aged 18 30) with T2DM, 10 age matched controls and 10 age and BMI matched controls.

The study involves two visits. Visit one data on anthropometric, demographic and psychological variables are collected. Participants complete a VO2 max test and undergo pre and post exercise blood sampling.

Visit two involves fasting blood samples and a detailed cardiac magnetic resonance imaging (MRI) with stress perfusion testing and an echocardiogram. Between visits participants wear an accelerometer for 1 week which allows for the objective measurement of physical activity.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Lifestyle change
2. Depression
3. Illness beliefs
4. Weight
5. Cardiovascular diseases (CVD) risk

Secondary outcome measures
1. Cardiac MRI and echocardiogram data
2. Maximal oxygen consumption (VO2) max
3. Physical activity measured by accelerometer
4. Inflammatory biomarkers: IL-6, TNF alpha, IL6 receptor, hsCRP
5. Biochemical outcomes: HbA1c, glucose, insulin, c-peptide, vitamin D, U&E, LFTs, TFTs
6. Psychological variables measured through questionnaire and semi-structured interviews
7. Anthropometric variables: Body mass index (BMI), waist circumference, blood pressure

Overall study start date
05/10/2009

Completion date
29/07/2011

Eligibility

Key inclusion criteria
1. Aged 18-30
2. Type 2 diabetes
3. Either male or female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Both

Target number of participants
UK Sample Size: 40

Key exclusion criteria
1. Estimated glomerular filtartion rate (eGFR) < 60mls/min
2. Asthma
3. Body weight more than or equal to 150kg
4. Contraindication to magnetic resonance imaging (MRI)

Date of first enrolment
05/10/2009

Date of final enrolment
29/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
Diabetes Research
Leicester Royal Infirmary
Infirmary Square
Leicester
England
United Kingdom
LE1 5WW

Sponsor type
Hospital/treatment centre

Website
http://www.leicestershospitals.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) ref: 77952

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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?
Results article	results:	01/07/2014		Yes	No