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Low glycaemic index diet for type 2 diabetics

Submission date	Recruitment status	[X] Prospectively registered
13/01/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/01/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/05/2019	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a condition where the pancreas doesn't produce enough insulin or the body's cells don't react to insulin, causing the blood sugar level to become too high. The aim of this study is to determine how the type of foods in a diet can affect blood sugar control and heart and blood vessel health in people with type 2 diabetes. The glycaemic index is a scale that ranks carbohydrate foods by how much they raise blood sugar levels compared to a standard food. In this study a low glycaemic index diet is compared to a standard healthy high fibre diet.

Who can participate?
Patients aged over 21 with type 2 diabetes

What does the study involve?
Participants are randomly allocated to be given dietary advice on either a low glycaemic index diet or a high fibre diet. They are required to keep a 7-day food record every 3 months throughout the 3-year study. Blood tests and body measurements are carried out every 3 months. Participants undergo MRI and ultrasound scans to look at the walls of the carotid arteries, the largest blood vessels in the neck. Retinal photographs are taken to look at the arteries in the eye. The MRI, ultrasound, and eye tests are done at the beginning of the study, after 1 year, and at the end (3 years).

What are the possible benefits and risks of participating?
This study assesses whether this dietary help can improve risk factors for heart disease. This may not benefit participants, but may improve how patients are treated in the future. There are small risks with having blood drawn and if a contrast dye is used for the MRI, which are explained in the consent form.

Where is the study run from?
1. St Michael's Hospital (Canada)
2. University of Toronto (Canada)

When is the study starting and how long is it expected to run for?
February 2010 to August 2016

Who is funding the study?
Canadian Institutes of Health Research (Canada)

Who is the main contact?
Dr David Jenkins

Contact information

Type(s)
Scientific

Contact name
Dr David Jenkins

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01063374

Secondary identifying numbers
09-193; MCT-98825

Study information

Scientific Title
Low glycaemic index diets to improve glycaemic control and cardiovascular disease in type 2 diabetics: a randomised controlled trial

Study objectives
A low glycaemic index diet will improve glycaemic control and plaque build-up in type 2 diabetics, compared to a high fibre diet.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Michael's Hospital Research Ethics Board, 16/12/2009, ref: REB09-093

Study design

Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Participants will be randomly assigned to receive dietary counselling for either a low glycaemic index diet, or a high cereal fibre diet for a three year period. Subjects will be followed for 3 years after starting the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 15/09/2016:
Plaque volume, assessed by MRI at 1 and 3 years

Previous primary outcome measures:
1. Carotid intima media thickness
2. HbA1c
3. Plasma glucose and lipids
Magnetic resonance imaging (MRI) of intima media will take place at 0, 1 year, and 3 years. Blood tests and clinic visits will take place every 3 months during the 3 years.

Secondary outcome measures
Current secondary outcome measures as of 15/09/2016:
1. Intima media thickness, assessed by 3D carotid ultrasound at 1 and 3 years
2. Plaque morphology measured at 1 and 3 years
3. HbA1c measured every 3 months for 3 years
4. Serum lipids measured every 3 months for 3 years
5. Blood pressure measured every 3 months for 3 years
6. Serum fasting glucose measured every 3 months for 3 years

7. Creatinine, urea, and C-peptides in 24 hour urine collection measured at 1 and 3 years
8. Anthropometric measures (weight, waist and hip circumference), measured every 3 months for 3 years
9. Retinal photography measured at 1 and 3 years

Previous secondary outcome measures:
1. Anthropometric measures
2. Blood and urine tests
Blood tests and clinic visits will take place every 3 months during the 3 years.

Overall study start date
01/02/2010

Completion date
01/08/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/09/2016:
1. Type 2 diabetes diagnosed for greater than 6 months
2. Men and women aged over 21 years
3. Stable dose of hypoglycaemic medication
4. HbA1c between 6.5 and 8.0 at screening, and pre-study visit
5. Stable weight
6. Family physician and valid health card
7. Stable dose of lipid medication, if prescribed
8. Stable dose of blood pressure medication, if prescribed
9. Ability to keep written food records, use digital food scale

Previous inclusion criteria:
1. Type 2 diabetes dignosed for greater than 6 months
2. Men and post-menopausal women, aged over 21 years
3. Stable dose of hypoglycaemic medication
4. HbA1c between 6.5 and 8%
5. Stable weight
6. Family physician and valid health card
7. Stable dose of lipid medication, if prescribed
8. Stable dose of blood pressure medication, if prescribed
9. Ability to keep written food records, use digital food scale

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

160

Key exclusion criteria
1. Insulin, steroids, or warfarin
2. Gastrointestinal disease
3. Major cardiovascular event in past 6 months
4. Major surgery in past 6 months
5. Liver disease, hepatitis B or C
6. Renal failure
7. Major debilitating disorder
8. Serum triglycerides greater than 6 mmol/L
9. History of cancer (except non-melanoma skin cancer)
10. Pre-menopausal women
11. Food allergies to study foods
12. Blood pressure above 145/90 mmHg
13. Acute or chronic infections
14. Chronic inflammatory diseases
15. Inability to undergo magnetic resonance imaging (MRI)
16. Any other condition which make one unsuitable for the study

Date of first enrolment
01/02/2010

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
Canada

Study participating centre
St Michael's Hospital
Toronto
Canada
M5C 2T2

Sponsor information

Organisation
St Michael's Hospital (Canada)

Sponsor details
30 Bond St
Toronto

Canada
M5B 1W8

Sponsor type
Hospital/treatment centre

Website
http://www.stmichaelshospital.com

Organisation
University of Toronto (Canada)

Sponsor details
Department of Nutritional Sciences
Faculty of Medicine
150 College St, Room 340
Toronto
Canada
M5S 3E2

Sponsor type
University/education

Website
www.utoronto.ca

Organisation
St. Michael's Hospital

Sponsor details

Sponsor type
Not defined

Website
http://www.stmichaelshospital.com/

ROR
https://ror.org/04skqfp25

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (ref: MCT-98825)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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?
Protocol article	protocol	07/07/2016		Yes	No
Interim results article	baseline data	22/03/2017		Yes	No