# Low glycaemic index diet for type 2 diabetics

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

#### 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

61 Queen St. East, 6th Floor Toronto Canada M5C 2T2

## Additional identifiers

#### ClinicalTrials.gov (NCT)

NCT01063374

#### Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

Current primary outcome measures as of 15/09/2016:

Plague 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.

## Key secondary outcome(s))

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.

#### 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** 

### Healthy volunteers allowed

No

### Age group

Adult

#### Sex

All

#### 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)

## Organisation

University of Toronto (Canada)

#### Organisation

St. Michael's Hospital

#### **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 - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

Canada

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

#### **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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes