

Low glycemic index diets in type two diabetic subjects treated with oral agents

Submission date 19/07/2004	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/07/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/04/2008	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT 67894

Study information

Scientific Title

Study objectives

Low glycemic index diets will improve glycemic control in type two diabetic subjects treated with oral agents.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from:

1. St. Michael's Hospital REB (ref: 04-021c)
2. University of Toronto REB (ref: 17914)

As of 20/08/2007: The sample size was approved to be increased to 200 subjects by St. Michael's Hospital Ethics Board on 31 October 2006 (REB#04-021).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Type two Diabetes

Interventions

Control:

Advice to consume a high cereal fibre, whole grain, normal Glycemic Index (GI) diet (mean GI = 80).

Test:

Advice to consume a low glycemic index diet (mean GI less than 70) based on differences in the particle size and nature of the study foods but with similar fibre content to the 'control diet'.

For further information, please contact the principal investigator Dr David Jenkins or the principal co-investigator Dr Cyril Kendall at the address listed below.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Treatment difference in the change in HbA1c accross treatments.

Secondary outcome measures

1. Fasting blood glucose
2. Fasting insulin
3. High sensitivity C-Reactive Protein (hs-CRP)
4. Oxidized Low Density Lipoprotein (LDL)
5. LDL particle size
6. High Density Lipoprotein (HDL)
7. Change in body weight or oral hypoglycemic agents

Overall study start date

01/09/2004

Completion date

01/06/2007

Eligibility**Key inclusion criteria**

1. Men and postmenopausal women with type two diabetes, greater than or equal to 18 years old
2. On oral hypoglycemic agents
3. Have fasting plasma HbA1c concentrations between 6.5 and 8.0%

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Target number amended as of 20/08/2007: 200. Target number at time of registration: 144.

Key exclusion criteria

1. Diabetic complications: clinically significant gastroparesis, retinopathy, nephropathy, neuropathy, hepatic disease or Coronary Heart Disease (CHD) (major coronary event)
2. Major surgery less than six months prior to randomisation, treatment with insulin, acarbose, steroids, or having serum triglycerides more than or equal to 4.0 mmol/L

Date of first enrolment

01/09/2004

Date of final enrolment

01/06/2007

Locations**Countries of recruitment**

Canada

Study participating centre

University of Toronto

Toronto, ON

Canada

M5S 3E2

Sponsor information**Organisation**

Canadian Institutes of Health Research (CIHR) (Canada)

Sponsor details

Room 97

160 Elgin Street

Address locator: 4809A

Ottawa, ON

Canada

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+1 888 603 4178

info@cihr-irsc.gc.ca

Sponsor type

Research organisation

Website

<http://www.cihr-irsc.gc.ca/>

ROR

<https://ror.org/01gavpb45>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT 67894)

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