ISRCTN36443696 https://doi.org/10.1186/ISRCTN36443696

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

Submission date	Recruitment status	[X] Prospectively registered
19/07/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/07/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2008	Nutritional, Metabolic, Endocrine	[ ] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Treatment difference in the change in HbA1c accross treatments.

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
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Sponsor information

Organisation
Canadian Institutes of Health Research (CIHR) (Canada)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration