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Long-term effect of altering the source and amount of dietary carbohydrate in type 2 diabetes

Submission date	Recruitment status
24/02/2006	No longer recruiting
Registration date	**Overall study status**
24/02/2006	Completed
Last Edited	**Condition category**
05/04/2012	Nutritional, Metabolic, Endocrine

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

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
NCT00223574

Secondary identifying numbers

MCT-44205

Study information

Scientific Title
Comparison of the long-term effect of reducing the glycaemic index versus reducing the amount of dietary carbohydrate in type 2 diabetes: a randomised controlled trial

Acronym
CCD (Canadian trial of dietary Carbohydrates in Diabetes)

Study objectives
To compare the effects, in subjects with diabetes treated by diet alone, of reducing glycaemic load by replacing high glycaemic index (GI) starchy foods with low GI starchy foods (i.e. reducing diet GI) versus low carbohydrate foods rich in monounsaturated fat (i.e. reducing the amount of dietary carbohydrate).

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Toronto Research Ethics Board, St Michael's Hospital gave approval on the 19th December 2001

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

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
Group 1 - high carbohydrate, high glycaemic index starchy foods (control); duration 12 months
Group 2 - high carbohydrate, low glycaemic index starchy foods; duration 12 months
Group 3 - low carbohydrate foods, high in monounsaturated fat; duration 12 months

Trial details received: 12 Sept 2005

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Glycated haemoglobin (A1c) measured at -2 and 0 weeks and at 3, 6, 9 and 12 months after randomisation (measure at 12 months is done twice; at 50 and 52 weeks).

Secondary outcome measures
1. Fasting plasma: total, low density lipoprotein (LDL) and high density lipoprotein (HDL) cholesterol, triglycerides, Apolipoprotein A (Apo A), Apolipoprotein B (Apo B), C-reactive protein (CRP), free fatty acids (FFA), glucose, insulin, acetate, propionate, butyrate all measured at baseline and at 1, 3, 6, 9 and 12 months after randomisation
2. Oral glucose tolerance: area under curve (AUC) for glucose and insulin, two-hour glucose, insulinogenic index measured at baseline and at 3, 6 and 12 months after randomisation. Eight-hour metabolic profile for glucose, insulin, triglycerides and FFA measured at baseline and 12 months after randomisation.
3. Body weight, waist circumference, blood pressure measured at 2 - 4 week intervals throughout the trial
4. Quality of life and activity index measured at baseline and 12 months after randomisation
5. Intakes of carbohydrate, fiber, starch, sugars, total fat, saturated fat, polyunsaturated fatty acids (PUFA) and monounsaturated fatty acids (MUFA), protein, glycaemic index and glycaemic load measured using a three-day food record two times at baseline and 1, 3, 6, 9 and 12 months after randomisation

Overall study start date
01/04/2001

Completion date
31/01/2004

Eligibility

Key inclusion criteria
1. Male or non-pregnant females
2. Aged 40 - 70 years old
3. Body mass index less than 40 kg/m^2
4. HbA1c less than or equal to 8.5%

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
168

Key exclusion criteria
1. Absence of diabetes
2. Age less than 40 years or greater than 70 years
3. Pregnancy or lactation
4. Body mass index greater than or equal to 40 kg/m^2
5. Use of any hypoglycaemic or anti-hyperglycaemic drug
6. HbA1c greater than 8.5%
7. Major cardiovascular event (stroke, myocardial infraction) or surgery within six months
8. Serum triglycerides greater than 10 mmol/l
9. Presence of other major debilitating disorder such as liver disease, renal failure, cancer
10. Presence of gastrointestinal disorder or use of a drug which is likely to alter gastrointestinal motility or nutrient absorption
11. Substance abuse
12. Simultaneous participation in another clinical trial

Date of first enrolment
01/04/2001

Date of final enrolment
31/01/2004

Locations

Countries of recruitment
Canada

Study participating centre
Department of Nutritional Sciences
Toronto
Canada
M5S 3E2

Sponsor information

Organisation
University of Toronto (Canada)

Sponsor details
27 King's College Circle
Toronto
Canada
M5S 1A1

Sponsor type
University/education

Website
http://www.utoronto.ca/

ROR
https://ror.org/03dbr7087

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-44205)

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	01/01/2008		Yes	No
Results article	disposition index results	01/09/2008		Yes	No
Results article	results	01/03/2013		Yes	No