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The effect of a combination of dietary factors (viscous fibers, vegetable proteins and plant sterols) on cholesterol reduction in hyperlipidemic subjects

Submission date	Recruitment status	[X] Prospectively registered
10/08/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/08/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2021	Nutritional, Metabolic, Endocrine	

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-68767

Study information

Scientific Title
The effect of a combination of dietary factors (viscous fibers, vegetable proteins and plant sterols) on cholesterol reduction in hyperlipidemic subjects

Study objectives
Lowering foods is more effective than current conventional low saturated fat diets.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Michael's Hospital - Research Ethics Board, 16/09/2004

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
Hypercholesterolemia

Interventions
Test group: soy foods, viscous fiber foods (oats and barley etc.), almonds and other nuts, plant sterol margarine prescribed as routine advice or intensive advice
Control group: low saturated fat, high fruit, vegetables and whole grain cereal advice

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

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Viscous fibers, vegetable proteins and plant sterols

Primary outcome measure
LDL-cholesterol

Secondary outcome measures
Total: High-Density Lipoprotein (HDL) cholesterol, TG, HDL-C, C-Reactive Protein (CRP), Homocysteine, glucose, insulin, waist circumference, blood pressure (BP), diet composition, body weight, and red cell fragility and plant sterol concentrations

Overall study start date
01/10/2005

Completion date
30/09/2007

Eligibility

Key inclusion criteria
1. 330 persons with hiperlipidemia of both sex, age groups 18 and older
2. Men and post menopausal women with Low-Density Lipoprotein (LDL)-cholesterol levels within 30% of their target goals who are prepared to make a serious commitment to dietary change

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
330

Key exclusion criteria
1. Body mass index (BMI) >32 kg/m^2
2. Recent weight loss or gain
3. Recent stroke
4. Myocardial Infarction (MI)
5. Familial hypercholesterolemia, secondary causes of hypercholesterolemia (e.g.

hypothyroidism unless treated, renal or liver disease)
6. Cholesterol lowering medications
7. Triglyceride (TG) less than 4.5, blood pressure (BP) more than 145/90
8. Diabetes or major disability or disease, including liver disease, renal failure or cancer

Date of first enrolment
01/10/2005

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
Canada

Study participating centre
University of Toronto
Toronto, Ontario
Canada
M5S 3E2

Sponsor information

Organisation
University of Toronto (Canada)

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

Sponsor type
University/education

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-68767)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		01/01/2008	27/10/2021	Yes	No