

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

Submission date 10/08/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 10/08/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/10/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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) $>32 \text{ kg/m}^2$
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