

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

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<b>Registration date</b> 10/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/10/2021	<b>Condition category</b> 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

Dr Cyril W.C. Kendall

### Contact details

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## Additional identifiers

### Protocol serial number

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

## Study type(s)

Treatment

## 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(s)

LDL-cholesterol

## Key secondary outcome(s))

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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)

### 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

### 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?
<a href="#">Results article</a>		01/01/2008	27/10/2021	Yes	No