Cholesterol Absorption Inhibition Study in humans after single intake of cholesterol lowering margarine, Unilever Study 09030-V, Study name: CASTELL

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Cholesterol absorption inhibition (%) calculated from plasma concentration vs. time curves from labeled cholesterol, for the PS or PSE containing products, compared to a control product without PS or PSE.

Ethical review	Approved WMO
Status	Pending
Health condition type	Lipid metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON34622

Source
ToetsingOnline

Brief title
CASTELL

Condition

- Lipid metabolism disorders

Synonym
mild hypercholesterolemia, slightly elevated cholesterol

Research involving
Human

Sponsors and support

Primary sponsor: Unilever

Source(s) of monetary or material Support: Unilever

Intervention

Keyword: absorption, cholesterol, margarine, plantsterols

Outcome measures

Primary outcome

Enrichments of labeled cholesterol isotopes as determined by GCMS and IRMS in plasma. Fractional absorption is determined by the ratio of the two isotopes in plasma cholesterol over 7 days.

Secondary outcome

PK parameters (for labeled cholesterol) derived from plasma curves (Cmax, Tmax, cholesterol pool, flux).

Study description

Background summary

Consuming Plant Sterols (PS) fortified foods is widely accepted as easy to apply, life-style change to combat modestly elevated plasma cholesterol concentrations. PS are typically formulated as PS fatty acid ester (PSE) from margarines. Such products could further be improved to increase impact at a population level. To explore this, PS will be formulated in a new innovative type spread. The use of PS (instead of PSE) and the innovative process are two changes from the current product with PSE (Reference). To confirm that the new formulation and change from PSE to PS results in a comparable cholesterol absorption inhibition as the reference product a dual isotope cholesterol study is planned, prior to any larger efficacy study.
Such information is pivotal in the further development of the new spread with consumer relevant benefits, such as: lower in saturated fats, increased formulation space to include future relevant ingredients, and a more sustainable process.

Study objective

Cholesterol absorption inhibition (%) calculated from plasma concentration vs.

time curves from labeled cholesterol, for the PS or PSE containing products, compared to a control product without PS or PSE.

Study design

Acute, single dose, double-blind, randomized, cross-over.

Intervention

Three study periods during which a single dose of either Test, Reference or Control (regular Becel light) spreads will be consumed together with standard breakfast. At each study period, 50 mg of D7-cholesterol is added to the meal and 30 mg of 13C-cholesterol is injected to measure cholesterol absorption. Before and four times after consumption of each spread, blood samples will be taken at 24 h intervals up to 7 days.

Study burden and risks

Total amount of blood drawn excluding screening, is 3 x 5 x 13.5 mL = 202.5 mL over a period of 3 months.

Subjects are requested to pay 16 visits to the center, of which;
- 1 screening visit, including blood draw (13.5 mL) and a physical examination,
- 3 visits at start of each period including an iv injection, one blood draw and administration of product and the orally dosed label (capsule),
- and per period, 4 more visits over 168 hr in total for blood draw.

For each period a diary is filled out to record dietary habits during the study period.

The insertion of the canula for iv injection per period, and/or the venapunctures for blood draws throughout each period can cause discomfort and possibly local brusing.

There is no risk known associated to the consumption of regular or plant sterol enriched margarines.

The study delivers no immediate benefit for the participating subjects, there is only a research benefit on the long term from the data obtained.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Apparently healthy males aged 20 - 65 y
- BMI 20-27 kg/m2
- LDL-C levels between 3.0 * 5.0 mmol/L, triglycerides < 3.0 mmol/L
- Non-smoker (tobacco, marijuana).
- No use of medication which interferes with study measurements
- Consumption <=< 21 alcoholic drinks in a typical week.
- No reported participation in another nutritional or biomedical trial 3 months before the pre-study examination or during the study.
- No reported participation in night shift work during the study.

Exclusion criteria

- Unwilling to refrain from consumption of plant sterol or stanol containing products, e.g. Becel pro.activ, Benecol, etc one week before and during the study
- Plasma lipid profile which indicates deviating lipid / cholesterol homeostasis
- Evidence of severe cardiovascular, respiratory, urogenital, gastrointestinal/ hepatic, hematological/ immunologic, HEENT (head, ears, eyes, nose, throat), dermatological/

connective tissue, musculoskeletal, metabolic/nutritional, endocrine, neurological/ psychiatric diseases, allergy, major surgery and/or laboratory assessments which might limit participation in or completion of the study protocol.
- Gastrointestinal or hepatic disorders influencing gastrointestinal absorption or transit, including gallstones or biliary diseases.
- History of surgery related to the gastro-intestinal tract
- On a medically prescribed or weight reduction diet
- Recreational (intravenous) drug use.
- The use of psychotropic drugs, including: benzodiazepines or alcohol in excess of 21 units/ week for males
- Concomitant medication that may modulate gastro-intestinal secretions and pH (e.g. antacids, proton-pump-inhibitors, prostaglandins, anticholinergic agents, H2-receptor antagonists)
- Concomitant medication that can alter gastric emptying (e.g. metoclopramide, cisapride, domperidone and erythromycin, anticholinergics, tricyclic antidepressants, narcotic analgesics, adrenergic agents, calcium channel blockers)
- Concomitant medication that can alter intestinal transit (e.g. loperamide, chemical/ osmotic/bulk laxatives), or influence satiety/energy intake (e.g. sibutramine, glucocorticoids, anabolic steroids)
- Intolerance or allergy for test product.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2010
Enrollment:	18
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL31924.018.10
Other	will follow asap