Health effects of CLA versus industrial trans fatty acids

Published: 11-09-2007 Last updated: 14-05-2024

To investigate what the effect is of CLA on blood lipoproteins, inflammatory markers, blood pressure and insulin status in human volunteers relative to industrial trans fatty acids and to oleic acid

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30632

Source ToetsingOnline

Brief title CLARINeT=CLA randomized intervention trial

Condition

• Other condition

Synonym risk markers for cardiovascular disease

Health condition

indicatoren voor hart- en vaatziekten

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit **Source(s) of monetary or material Support:** Ministerie van OC&W,KNAW,SOVG;hartstichting

Intervention

Keyword: cholesterol, CLA, trans fatty acids

Outcome measures

Primary outcome

Blood:

- Total and HDL cholesterol, Apo B, LDL cholesterol according to Friedewald
- Triglycerides

Secondary outcome

Blood:

- Insulin status markers, such as HOMA and revised QUICKY
- Inflammatory markers, such as C-RP, IL-6, E-selectin, MCP-1, s-TNF-R1,
- s-TNF-R2, IFg
- Fatty acid composition of cholesteryl esters [Zock, 1997] and erythrocytes as

an objective measure of compliance with diets

• Proteomics (DNA)

Urine: iso-prostanes

Blood Pressure and heart rate

Study description

Background summary

High intakes of trans fatty acids increase the risk of coronary heart disease and authorities worldwide are attempting to limit their intake. However, there are two sources of trans fatty acids with possibly different effects on health. So-called *industrial* trans fatty acids are produced by partial hydrogenation of vegetable and fish oils. The unfavourable effects of these trans fatty acids are well established: they raise LDL-cholesterol, depress HDL cholesterol, and are associated with increased coronary heart disease (fig. 1A) [Ascherio, 1999]. Trans fatty acids also occur naturally in the dairy and body fat of ruminant animals including cows, and these ruminant trans fatty acids are now the dominant form in the European diet. The effects of dairy trans fatty acids on blood lipids in humans have not been studied, and their intake is associated with less rather than more coronary heart disease in several studies (fig. 1B) [Willett WC, 1993; for a review see Weggemans, 2004]

Study objective

To investigate what the effect is of CLA on blood lipoproteins, inflammatory markers, blood pressure and insulin status in human volunteers relative to industrial trans fatty acids and to oleic acid

Study design

It will be a double-blind randomized multiple cross-over trial with 3 treatments:

- CLA
- industrial trans fatty acids (as a positive control)

• oleic acid (Cis 18:1, the monounsaturated fatty acid in unhydrogenated vegetable oils) as a reference fat.

Each volunteer receives each diet for three weeks, in random order, for a total of 9 weeks. Three weeks is sufficient to reach new stable lipoprotein levels.

Intervention

It will be a double-blind randomized multiple cross-over trial with 3 treatments:

- CLA
- industrial trans fatty acids (as a positive control)

• oleic acid (Cis 18:1, the monounsaturated fatty acid in unhydrogenated vegetable oils) as a reference fat.

Each volunteer receives each diet for three weeks, in random order, for a total of 9 weeks. Three weeks is sufficient to reach new stable lipoprotein levels. Location: Wageningen University, Division of Human Nutrition, the Netherlands. Almost all food (90% of energy) is provided to the participants, as described earlier [Mensink, 1990]. Duplicate blood samples are taken in the last week of each dietary period.

The margarines will be produced and coded with random codes by NIZO so that the

study will be double-blind. Analyses of the margarines before the trial will also be blinded. The codes will be broken only after the data have been analysed and all authors have agreed on the essential tables and figures.

Study burden and risks

The risks are low, burden is quite heavy because the subjects have to eat the provided food for 9 weeks. However, it is a normal, nice eatable diet.

Contacts

Public Vrije Universiteit

De Boelelaan 1085 1081 HV Amsterdam Nederland **Scientific** Vrije Universiteit

De Boelelaan 1085 1081 HV Amsterdam Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy volunteers aged 18 to 65 years

4 - Health effects of CLA versus industrial trans fatty acids 24-06-2025

Exclusion criteria

Subjects with chronic disease, such as diabetes or cardiovascular disease, and pregnant women will be excluded. Other exclusion criteria are abnormal cholesterol or triglyceride concentrations, use of cholesterol lowering medication, unusual dietary requirements, including high alcohol intakes and BMI > 30.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	26-09-2007
Enrollment:	60
Туре:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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 CCMO **ID** NL15599.081.06