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Rationale and design of the TRANSFACT project phase I: A study to assess the effect of the two different dietary sources of *trans* fatty acids on cardiovascular risk factors in humans

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Abstract

Background: Detrimental effects of consumption of industrial *trans* fatty acids (TFA) from partially hydrogenated vegetable oils (PHVO) on cardiovascular disease (CVD) risk factors are well documented. However, very little information is available on the effect of natural sources of TFA coming from milk fat, dairy products and ruminant meat. In fact, due to the naturally low level of TFA in milk fat, it is almost impossible to conduct a clinical trial with a limited number of subjects (<200).
Methodology: To compare the effects of industrial and natural dietary sources of TFA, two specific test fats have been designed and produced. A substantial amount of milk fat (130 kg) enriched in TFA has been produced by modification of the cow's diet and selection of cows with the highest TFA content. The level obtained was approximately 4- to 7-fold higher than typically present in milk fat (~ 20 instead of 3–6 g/100 g of total fatty acids). The control fat is composed of PHVO balanced in saturated fatty acids (lauric, myristic and palmitic). Both experimental fats contain about 20–22% of monounsaturated TFA and the volunteers' daily experimental fat intake (54 g), will represent about 12.0 g/day of TFA or 5.4% of the daily energy (based on 2000 kcal/day). These two test fats have been incorporated into food items and will be provided to 46 healthy subjects under a randomised, double blind, controlled, cross-over design. The primary outcome is high-density lipoprotein cholesterol (HDL-C), which is an independent risk factor for CVD. Other parameters such as low-density lipoprotein cholesterol (LDL-C), very low-density lipoprotein cholesterol

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(VLDL-C), and HDL-C level and subclasses will be also to be evaluated.
Conclusion: We have shown that it is technically feasible to perform a clinical trial on the comparative effects of natural and industrial sources of TFA isomers on CVD risk factors. Results are expected by mid-2006.

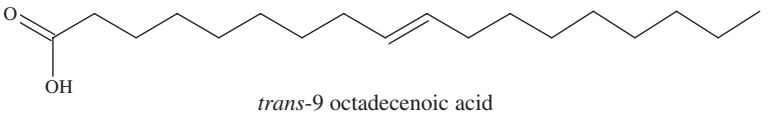
Keywords: Cardiovascular disease; Milk fat; Public health nutrition; *trans* fatty acid

1. Introduction

Among dietary fats, fatty acids are present as saturated and unsaturated fatty acids. Generally, unsaturated fatty acids have their double bonds in *cis* configuration. Dietary fats also contain *trans* fatty acids (TFA). A *trans* double bond is most commonly introduced into a fatty acid chain either by chemical processes during the formation of partially hydrogenated vegetable oils (PHVO; technologically induced TFA) or in the formation of intermediates during rumen biohydrogenation (natural TFA) [1–3]. PHVO are used extensively in the production of many industrially prepared foods such as margarine, cooking fats, culinary and bakery products [1,2]. Natural sources of TFA are present in ruminant lipids supplied in the diet by milk, dairy products and ruminant meat, i.e. beef, lamb. These two dietary TFA sources are characterized by different TFA isomeric distributions and content [1,2]. *trans* Monounsaturated fatty acid (FA) isomers with 18 carbons chain length (*trans*-18:1 acids) are the predominant TFA present in the human diet and structures of the three main dietary isomers are shown in Fig. 1. The use of PHVO in margarine production has markedly decreased since the middle of the 1990s in Europe, as several scientific publications have pointed out adverse effects, particularly in relation with cardiovascular risk factors [4–9].

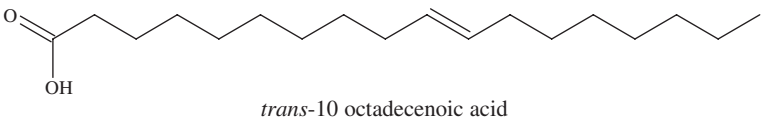
In the production of PHVO the goal is to obtain a fat with specific structural properties that has increased stability and provides better product shelf-life. This industrial process converts liquid vegetable oils into solid or semi-liquid fats. Fully hydrogenated vegetable oils contain only traces of TFA. However, PHVO can contain 5% to 60% TFA. The two main TFA isomers in PHVO are *trans*-9 18:1 (elaidic) and *trans*-10 18:1 fatty acid isomers [1–3].

In ruminants, TFA isomers are formed as intermediates during biohydrogenation of dietary unsaturated fatty acids (e.g. linoleic and α-linolenic acids) by rumen bacteria [10–13]. Vaccenic acid (*trans*-11 18:1) is the most abundant intermediate produced during rumen biohydrogenation and it is the major TFA in ruminant fat (3). A more complete characterization of differences in the content and isomeric distribution between industrial and natural sources of TFAs is presented in Table 1 [1].

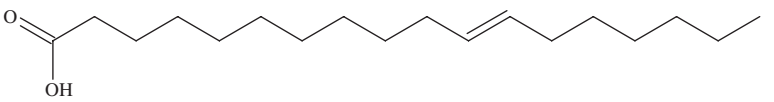


trans-9 octadecenoic acid

(elaidic acid)



trans-10 octadecenoic acid



trans-11 octadecenoic acid

(vaccenic acid)

Fig. 1. Chemical structures of *trans*-9 (elaidic), *trans*-10, *trans*-11 (vaccenic) octadecenoic acid isomers. Vaccenic (*trans*-11 18:1) acid is the main TFA isomer occurring in milk fat while elaidic (*trans*-9 18:1) acid, the main TFA present in partially hydrogenated vegetable oils.