

# Bioavailability and metabolic effects in humans of n-3 polyunsaturated fatty acids and conjugated linoleic acid after consumption of naturally enriched cow milk

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<b>Registration date</b> 26/02/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/02/2010	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

cb0603-feiraco-ul02

## Study information

**Scientific Title**

Bioavailability and metabolic effects in humans of n-3 polyunsaturated fatty acids and conjugated linoleic acid after consumption of naturally enriched cow milk: a randomised double blind parallel group trial

**Study objectives**

Including linseed in the feed of milk-producing animals provides polyunsaturated fatty acids (PUFA), mainly linoleic and alpha-linoleic acids, which rumen bacteria transform into longer-chain (and more unsaturated) derivatives and cis-9, trans-11 conjugated linoleic acid (CLA) that are incorporated into milk. Both n-3 PUFA and CLA are suggested to have beneficial effects on cardiovascular risk and adiposity, respectively.

Our hypothesis is that, compared to the daily intake during 6 weeks of 500 ml of milk obtained from cows eating regular feed, intake during 6 weeks of 500 ml of milk from similar cows fed 5% extruded linseed will be associated with an increase of n-3 PUFA and CLA in plasma, thus demonstrating their bioavailability from milk.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Institutional Review Board of the Hospital Clinic of Barcelona approved on the 7th April 2009 (ref: 2009/4920)

**Study design**

Randomised double-blind parallel group feeding intervention study

**Primary study design**

Interventional

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Nutrition

**Interventions**

Experimental group: 500 ml/day of test milk

Control group: 500 ml/day of regular milk

The methodology is the same for participants in the two arms of the study, except for the milk product given (milk naturally enriched in n-3 fatty acids and CLA in one arm, plain milk in the other arm). A requisite for entry is that participants are overweight and do not consume fermented milk products or fatty fish more than once per week. They are instructed to follow their usual diet and physical activity throughout the study, which lasts 6 weeks, and consume 500 ml per day of the corresponding milk, which is provided in 1 litre containers labelled as A or B to mask the composition. On week -1 and week 5 participants fill in 7-day food records, and on days 1 and 42 they undergo medical questionnaires, anthropometric and blood pressure measurements, and venipuncture. Also on day 42 they bring empty milk containers to recount

and measure adherence. There is no further follow-up after 6 weeks, but participants are given copies of biochemical analyses and will be given a brief explanation of the results of the study once they become available.

Anthropometry (height, weight and waist circumference) and blood pressure are determined by standard methods. 7-day food records are translated into nutrients by using the Food Processor, Version 8.44 software (ESHA Research, Salem, OR) adapted to nutrient databases of specific Mediterranean foods when appropriate. Blood glucose and lipids are analysed by standard enzymatic methods; safety haematological and biochemical analytes by standard clinical laboratory automated methods; and plasma fatty acids by gas chromatography.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Determination of plasma fatty acid content at baseline and after 6 weeks of consumption of experimental and control milks

### **Key secondary outcome(s)**

1. Medical record, including anthropometric measurements (height, weight and waist circumference) and blood pressure at baseline and end of treatment
2. Food, energy and nutrient intake assessed by 7-day food records prior to entry and on the last week of intervention
3. Blood chemistry, with safety profile (complete blood count, fasting blood glucose, creatinine, uric acid, alanine aminotransferase [ALT], aspartate aminotransferase [AST], gamma-glutamyl transferase [GGT], and total protein) and lipid profiles (total cholesterol, high density lipoprotein [HDL] cholesterol, low density lipoprotein [LDL] cholesterol and triglycerides) at baseline and the end of treatment

### **Completion date**

31/01/2010

## **Eligibility**

### **Key inclusion criteria**

1. Healthy men and women volunteers
2. Aged between 18 and 50 years
3. Overweight (body mass index [BMI] between 25.0 and 29.9 kg/m<sup>2</sup>)
4. Sign an informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Subjects with a prior history of cardiovascular disease, cancer, any severe chronic disease, psychiatric condition, alcoholism or drug abuse
2. Milk intolerance
3. Intake of fish oil capsules or fish oil enriched foods in the prior 3 months
4. Consumption of fatty fish more than once per week
5. BMI outside of pre-specified range

**Date of first enrolment**

01/05/2009

**Date of final enrolment**

31/01/2010

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**

Hospital Clinic de Barcelona

barcelona

Spain

08036

## **Sponsor information**

**Organisation**

Feiraco Lacteos S.L. (Spain)

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Feiraco Lacteos S.L. (Spain)

**Funder Name**

Spanish Ministry of Science and Innovation (Ministerio de Ciencia e Innovación [MICINN]) (Spain)

**Funder Name**

Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain)

**Funder Name**

CIBER fisiopatología de la obesidad y nutrición (CIBERobn) (Spain)

**Funder Name**

Spanish Ministry of Health (Spain) - Health Research Fund (Fondo de Investigaciones Sanitarias [FIS]) (ref: cd07/00083)

## Results and Publications

**Individual participant data (IPD) sharing plan****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="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes