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

Submission date 02/02/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 26/02/2010	**Overall study status** Completed	
Last Edited 26/02/2010	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 froms 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Can be found at http://www.ciberobn.es/media/faq/Oficina%20de%20Proyectos/HOJA%20DE%20INFORMACIÓN%20AL%20PARTICIPANTE%20%20Y%20CI.doc

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

Secondary outcome measures
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 lipopotein [LDL] cholesterol and triglycerides) at baseline and the end of treatment

Overall study start date
01/05/2009

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^2)
4. Sign an informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
38

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
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Sponsor information

Organisation
Feiraco Lacteos S.L. (Spain)

Sponsor details
Apartado 19
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Sponsor type
Industry

Website
http://www.feiraco.es/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration