

Informed consent form for the volunteer(s) to the study:

Effects of the ingestion of human, cow and modified cow milk, on glucose, amino acid and hormone responses in humans
Acronym: PROLAT

I've been invited by Prof. Paolo Tessari to participate into the study entitled:

"Effects of the ingestion of human, cow and modified cow milk, on glucose, amino acid and hormone responses in humans".

The aims of the study are to investigate the effects of ingestion of human and cow milk, either natural or modified, on glucose, amino acid and hormone responses in humans.

Milk of mammals is a complete food containing carbohydrates, lipids, proteins, peptides, vitamins, oligo-elements and water. Milk represents the first food in the nutrition and development of the neonate and a key nutritional compound throughout human life. I've been informed that the nutritional importance of milk is due to its complete and balanced content of key essential as well as non essential nutrients. AS a matter of fact, it contains: high biological value proteins, rich in essential amino acids; lipids; lactose (a sugar similar to glucose); minerals; vitamins; and energy, associated to the carbohydrate, protein and fat fractions.

Furthermore, milk exhibits specific functional properties, largely conveyed by the protein/peptide components. One property of milk is to stimulate hormone secretion, such as insulin, the incretins glucagon-like-polypeptide-1 (GLP-1) and gastric-inhibiting-peptide (GIP) (5), and insulin-like-growth factor-1 (IGF-1). The stimulation of these hormones enhances substrate utilization.

Milk from several species can be utilized in human nutrition, above all cow milk.

Milk composition is species-specific, with quantitative and qualitative differences involving all its nutrients. Compared to cow milk, human milk is richer in lactose (≈ 7.2 vs 4.9 g/100 mL), nearly equivalent in lipids and calories, but it contains $>50\%$ less protein, depending on the lactation period. The protein fraction(s) of human and cow milk exhibit marked qualitative and quantitative differences: in the former, the proteins are mainly in the soluble whey fraction, whereas in the latter the (insoluble) casein(s) is predominant.

Therefore, the aims of this study are to test, in young healthy volunteers, the effects of natural cow and human milk, as well as of the manipulation of the protein content in cow milk, on insulin, C-peptide, GLP-1 and GIP secretion, as well as on circulating amino acids. The protein content of cow milk will be modified with the purpose to match its composition, from a qualitative and/or quantitative standpoint, to that of human milk. Protein modification in cow milk will be accomplished by dilution with water, followed by additions of commercially-available cow milk protein fractions, in proper amounts to obtain the desired composition. Fat (from commercial cream) will be added as requested. Lactose and salts (sodium chloride, calcium, magnesium, from hospital solutions) will also be added with the aim to match as far as possible the compositions among the milks.

Therefore, all milk samples will maintain all the compositional characteristics (besides the proteins) of natural milk, and will accomplish the current regulation regarding its use in man.

I've been informed that the test will consist in the administration, under different occasions spaced by a ≥ 7 -day interval, of calibrated volumes of either human milk (provided by the Human Milk Bank of the Pediatric Dept. of the Padova University Hospital), or of cow milk, as well as of modified milk solutions, all containing the same amount of lactose.

At 08:00 after the overnight fast, a 20-g cannula will be inserted in an antecubital vein for blood withdrawal. After two baseline samples spaced by $\approx 10'$, the milk load will be administered over 2'-5'. Starting from the end of milk ingestion ($t = 0'$), blood samples were taken at min 5', 10', 20', 30', 60', 90', 120', 180', and 240'. The total amount of blood will not exceed ≈ 80 mL.

I'm fully aware that this study is relevant and that it requires my commitment for its completion. I've been informed that my participation to the study wouldn't be followed by any direct beneficial effects to participants, although it could improve our knowledge on the relationships between milk composition and metabolism as well as hormonal response(s).

I've been suggested to participate into all the four programmed tests, although I can withdraw from any of them anytime and for any reason.

Date: _____

The study responsible, Prof. Paolo Tessari, can be found at the following sites and addresses:

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Volunteer's signature: _____

Responsible's Signature: _____

Family name _____

Name _____

Date of Birth _____ / _____ / _____

Place of Birth _____

Address _____

Telephone _____

E mail _____