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Effect of different components in milk on bioavailability of phenolic acid in humans

Submission date
30/08/2011

Recruitment status
No longer recruiting

Registration date
14/09/2011

Overall study status
Completed

Last Edited
08/06/2017

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Antioxidants are substances that may prevent or delay some types of cell damage (oxidative stress). The human diet provides a wide range of plant-derived phenolics with antioxidant effects. The body's response to antioxidant-rich foods is determined by the bioavailability of the active molecules - the proportion which enters the circulation and so is able to have an active effect. However, phenolics are generally consumed in foods along with other nutrients such as proteins, fats and sugars. These nutrients may have an impact on the phenolics' bioavailability. In many countries, polyphenol-rich food like tea or fruit juice is usually consumed with milk. Although there still some discrepancies, many researchers have reported milk reduces the phenolics' bioavailability. However, the effect of the different components in milk on phenolics' bioavailability is not known. The aim of this study is to examine the role of different milk components (protein, lipid, lactose) on the phenolics' bioavailability.

Who can participate?
Healthy volunteers aged 18 - 65

What does the study involve?
Participants are asked to consume their regular diet while avoiding foods rich in polyphenols for 2 days before each study day. These foods include fruit, vegetables, high fibre products, and drinks such as tea, coffee, fruit juice and wine. On five different study days (with a 1-week break between them), participants are randomly allocated to one of five treatments: (a) jujube fruits and water; (b) jujube fruits and whole milk; (c) jujube fruits and skimmed milk; (d) jujube fruits and cream; (e) whole milk and water. Blood samples are collected from all participants 1, 2, 3, 4, 6, 8 hours later. Urine is collected 24 hours before each study day and over five time periods (0–2, 2–5, 5–8, 8-12 and 12–24 hours) after the drinks.

What are the possible benefits and risks of participating?
The results will show whether milk components affect the bioavailability of phenolics. There are no known risks to participants.

Where is the study run from?
China Agricultural University (China)

When is the study starting and how long is it expected to run for?
September 2011 to October 2011

Who is funding the study?
National Science and Technology Support Program (China)

Who is the main contact?
Prof. Fazheng Ren
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of different components in milk on bioavailability of phenolic acid in humans: a randomised crossover interventional study

Study objectives
The presence of fat in milk will offer more locations for protein linking with phenolics. It means that the effect of cream on phenolics bioavailability is through the presence of mik protein. Accordingly, the phenolics increase fat globule size during digestion will affect the lipid absorption. Furthermore, the effect of lactose and ion in milk on phenolics bioavailability in vivo is not yet evaluated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised crossover feeding intervention study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
The acute effects were assessed and compared on five different days (with a 1-week interval between them), using a Latin-square design. The participants were asked to consume their regular diet while avoiding foods rich in polyphenols for 2 days before each study day. These foods included fruit, vegetables, high fibre products, beverages such as tea, coffee, fruit juice and wine. On each study day, the participants arrived at 9am after an overnight fast. Baseline blood was sampled and then participants were randomly assigned to one of five treatments.

Treatments included:
1. 200g jujube fruits and 200ml water
2. 200g jujube fruits and 200ml whole milk
3. 200g jujube fruits and 200ml skimmed milk
4. 200g jujube fruits and 200ml cream
5. 200ml whole milk and 200ml water

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Phenolic acids in plasma and urine measured at 1, 2, 3, 4, 6, 8 hours after intervention

Secondary outcome measures
1. Serum triacylglycerols, total cholesterol, high density lipoprotein (HDL) cholesterol, low density lipoprotein (LDL) cholesterol
2. Total antioxidant capacity in plasma
3. Resistance of serum lipids to oxidation
The outcomes will be measured at 1, 2, 3, 4, 6, 8 hours after intervention

Overall study start date
17/09/2011

Completion date
29/10/2011

Eligibility

Key inclusion criteria
1. Healthy males or females
2. Aged 18 - 65

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Severe obesity, Body Mass Index (BMI) > 32 kg/m2
2. Metabolic and endocrine diseases
3. Malabsorption syndromes
4. Current smoking or smoking cessation for < 6 months
5. Alcohol abuse (> 40 g alcohol/d)
6. Pregnancy/lactation
7. Food allergy
8. Milk intolerance
9. Vegetarian
10. Blood donation or blood transfusion less than 3 months prior to the study
11. Major surgery within the 3 months preceding the study
12. Simultaneous participation in another drug trial and use of dietary supplements or any form of medication

Date of first enrolment
17/09/2011

Date of final enrolment
29/10/2011

Locations

Countries of recruitment
China

Study participating centre
17 Tsing Hua East Road
Beijing
China
100083

Sponsor information

Organisation
China Agricultural University (China)

Sponsor details
College of Food Science and Nutritional Engineering
17 Tsing Hua East Road
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Sponsor type
University/education

Website
http://www.cau.edu.cn/cie/en/

ROR
https://ror.org/04v3ywz14

Funder(s)

Funder type
Government

Funder Name
National Science and Technology Support Program (China) ref: 2011BAD09B03

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