

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

Submission date 30/08/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/09/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/06/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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 milk 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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

Completion date

29/10/2011

Eligibility

Key inclusion criteria

1. Healthy males or females
2. Aged 18 - 65

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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Sponsor information

Organisation

China Agricultural University (China)

ROR

<https://ror.org/04v3ywz14>

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration