

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 14/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 08/06/2017	<b>Condition category</b> 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

**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 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

**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/m<sup>2</sup>
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/04v3y wz14>

## **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