

# Do healthy people absorb cow-derived microRNAs from drinks?

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<b>Registration date</b> 07/02/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/03/2026	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Recent research has identified a new type of substance naturally found in foods that may play a role in nutrition and health. This substance is called microRNA and is naturally occurring in both plants and animals. microRNAs are thought to be involved in controlling the levels of substances produced by cells. Along with other foods, milk contains microRNAs within exosomes (bubbles released by cells). This study aimed to investigate whether people absorb immune-relevant microRNAs from cow's milk into the blood and whether these affect human immune responses.

### Who can participate?

Healthy adults who are not pregnant, smokers or intolerant to cow's milk.

### What does the study involve?

Participants drank five different drinks based on 1 litre of cow's milk or soy-based infant formula with a period of at least a week between each one. Some of the drinks contained extra cow's milk exosomes and some had the exosomes destroyed. Blood samples were taken immediately before the drink and at 3, 6 and 9 hours afterwards.

### What are the possible benefits and risks of participating?

There were no direct benefits to research participants. Minimal risks were anticipated for the participants. However, potential risks included intolerance to milk, fatigue due to blood draws, and risk of bruising. No other physical, psychological, financial, etc., risks were expected. Blood draws may make someone become anxious, light-headed, nauseous, or generally uneasy. All blood draws were performed by University of Nebraska-Lincoln Health Center phlebotomists (experts in taking blood samples) who have been trained and are experienced in dealing with subjects who may become anxious during blood draw procedures.

### Where is the study run from?

University of Nebraska-Lincoln (USA)

### When is the study starting and how long is it expected to run for?

October 2013 to June 2019

Who is funding the study?  
The Gerber Foundation (USA)

Who is the main contact?  
Dr Janos Zempleni  
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## Contact information

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**

## Study information

### Scientific Title

Bioavailability of immunomodulatory microRNAs from bovine milk exosomes and cytokine secretion by peripheral blood mononuclear cells ex vivo in humans

### Study objectives

Immune-related miRNAs in bovine milk exosomes are bioavailable and modulate immune responses in humans. Immunomodulatory microRNAs depend on co-stimulation with concanavalin A to elicit cytokine secretion by peripheral blood mononuclear cells ex vivo in humans

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 10/10/2013, University of Nebraska-Lincoln Institutional Review Board (IRB) (301 Canfield, PO Box 880433, Lincoln, NE 68588-0433, USA; +1 (402) 472-3123; unlresearch@unl.edu), ref: 20131013755FB

### Study design

Randomized crossover trial

### Primary study design

Interventional

### Study type(s)

Other

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

Relevance of bovine milk exosomes as bioactive food compounds and use of exosomes for drug delivery.

### Interventions

12 healthy adults received 5 different milk meals in a randomized cross-over design, with a washout period of at least 1 week between each meal. The milk meals were 1 l of 1% fat bovine milk, 1 l of 1% fat sonicated bovine milk (exosomes depleted), 1 l of soy infant formula, 1 l of soy infant formula fortified with bovine milk exosomes, and 1 l of 1% fat sonicated bovine milk and fortified with bovine milk exosomes (exosomes containing microRNAs depleted by ultrasonication and then exosomes isolated from 1 l of bovine milk added back to the sonicated milk). Blood samples were collected before and at timed intervals after consumption of the various milk meals for analysis of bioavailability of six immune-relevant microRNAs in plasma and secretion of cytokines by peripheral blood mononuclear cells ex vivo.

### Intervention Type

Other

### Primary outcome(s)

Levels of six immune-relevant microRNA found in bovine milk exosomes in plasma using real-time quantitative polymerase chain reaction (RT-qPCR) before (0 h) and at timed intervals (3, 6, and 9 h) after a milk meal

### **Key secondary outcome(s)**

1. Secretion of inflammation-related cytokines by cultured human peripheral blood mononuclear cells (PBMCs) collected before and 6 h after milk consumption and stimulated with or without Concanavalin A (Con A) was assessed using a customized Milliplex Map Human Cytokine /Chemokine Magnetic Bead Panel Immunoassay
2. Secretion of cytokines by PBMCs treated ex vivo with microRNA-loaded exosomes assessed using a customized Milliplex Map Human Cytokine/Chemokine Magnetic Bead Panel Immunoassay

### **Completion date**

06/06/2019

## **Eligibility**

### **Key inclusion criteria**

Healthy adults

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Total final enrolment**

0

### **Key exclusion criteria**

1. Pregnant women
2. Smokers
3. Persons with lactose and milk protein intolerance or gastrointestinal disorders

### **Date of first enrolment**

09/04/2015

### **Date of final enrolment**

30/11/2017

## **Locations**

### **Countries of recruitment**

United States of America

**Study participating centre**  
**University of Nebraska-Lincoln**  
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## Sponsor information

**Organisation**  
The Gerber Foundation

**ROR**  
<https://ror.org/03ggcx620>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Gerber Foundation

**Alternative Name(s)**  
The Gerber Foundation, GerberFdnWMI, The Gerber Companies Foundation, GF

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Trusts, charities, foundations (both public and private)

**Location**  
United States of America

## Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

### IPD sharing plan summary

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2020	10/06/2020	Yes	No
<a href="#">Results article</a>		21/01/2022	24/01/2022	Yes	No
<a href="#">Results article</a>		28/05/2025	11/03/2026	Yes	No