The effect of milk consumption on the blood microbiome (MAMI study) in healthy volunteers

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We have preliminary data from blood collected in other studies that indeed measuring blood microbiomes is more informative as sampling the corresponding faeces samples and we have built a bio-informatical pipeline that apparently allows its analysis...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57456

Source ToetsingOnline

Brief title MAMI study

Condition

• Other condition

Synonym microbiota, microflora

Health condition

microbiome

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: Healthy volunteers, Milk, The blood microbiome

Outcome measures

Primary outcome

Lactococcus DNA counts before, during and end of the milk-consumption

intervention.

Secondary outcome

Other microbiome DNA counts (bacteria, viruses and Archaea) in gut and blood

before and after milk consumption.

Study description

Background summary

The blood microbiome is a term used for harnessing the information present in circulating cell-free DNA with respect to organisms present in and on the body. Well known in this respect is that the gut microbiome, while of great importance in maintaining host homeostasis and metabolism, can be strongly affected spurious dietary alterations, provoking almost dramatical temporal intra- and inter-individual variations. Nevertheless, fecal probing of the microbiome remains the norm. The blood microbiome might be more stable, integrating microbial information of a longer time.

Study objective

We have preliminary data from blood collected in other studies that indeed measuring blood microbiomes is more informative as sampling the corresponding faeces samples and we have built a bio-informatical pipeline that apparently allows its analysis. The current study is meant to provide proof-of-concept in this respect.

Study design

Single arm intervention study

Intervention

The participants will abstain from consumption of any dairy product for ten days, and subsequently drink milk for consecutive 7 days (700 millimetre per day), while concomitant consumption of other dairy products is also allowed.

Study burden and risks

Milk consumption is generally regarded as safe.

Contacts

Public Erasmus MC, Universitair Medisch Centrum Rotterdam

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

3 - The effect of milk consumption on the blood microbiome (MAMI study) in healthy v ... 10-05-2025

Inclusion criteria

- Age 18-65 years
- 18.5 =< BMI < 25 kg/m2
- All genders are included.
- Not be lactose intolerant
- Willing to consume milk

Exclusion criteria

- Regular use medications such as antibiotics, steroids, beta blockers, and adrenergic-stimulating agents (self-report)
- Regular use prebiotic and/or probiotics apart from yoghurt and young soft cheese (self-report)
- Antibiotic intake in the previous months (self-report)
- Daily consumption of more than 10 cigarettes (self-report)
- Chronic diseases including type 2 diabetes, hypertension, fatty liver disease, cancer, or autoimmune disease (self-report)
- Internal diseases, including those of the gastrointestinal tract, lung, heart, vasculature, liver, and kidney (self-report)
- Eating disorder or unconventional eating habits (self-report)
- Participation in another study (self-report)
- Women: pregnancy and breastfeeding (self-report)

Study design

Design

Study type: Interventional	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	20-04-2025
Enrollment:	10

4 - The effect of milk consumption on the blood microbiome (MAMI study) in healthy v ... 10-05-2025

Type:

Anticipated

Ethics review	
Approved WMO Date:	06-05-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register CCMO ID NL88008.078.24