Disease occurrence And Inflammation in relation to Raw cow*s milk consumption in elderly people.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49627

Source ToetsingOnline

Brief title DAIRY

Condition

- Other condition
- Autoimmune disorders
- Hepatobiliary neoplasms malignant and unspecified

Synonym infectieziekten, Inflammation-related disease

Health condition

inflammatie-gerelateerde ziekten

Research involving

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Human

Sponsors and support

Primary sponsor: Wageningen Universiteit Source(s) of monetary or material Support: Ministerie van OC&W,FrieslandCampina

Intervention

Keyword: Ageing, Dairy, Immunity, Inflammation

Outcome measures

Primary outcome

The main endpoint of the cohort study is the prevalence and incidence over

time (if budget allows) of inflammation-related disease. The main study

parameter of the feasibility study is the difference in age-related

inflammatory markers IL-6, CRP, and sVCAM in serum between the two milk groups

(mainly raw versus mainly UHT-processed cow*s milk).

Secondary outcome

The secondary outcome of the cohort study is the prevalence and incidence over

time (if budget allows) of auto-immune and infectious disease. The secondary

outcomes of the pilot study are differences and variances in serum levels of

the additional inflammatory markers TNF-a, sICAM-1, IL1RA.

Study description

Background summary

The global incidence of asthma, inflammation-related and autoimmune diseases is rising sharply. Milk and dairy-based products have been shown to have beneficial effects on the levels of pro-inflammatory mediators, and inverse associations have been described between dairy consumption and risk of inflammation-related diseases, such as type 2 diabetes, colorectal cancer, and Alzheimer*s disease. More specifically, evidence suggests early-life exposure to raw cow*s milk contributes to protection against allergies, asthma, and respiratory tract infections. Raw cow*s milk is suggested to contain immunomodulating food allergens and bacteria that are otherwise destroyed or altered by processing of milk. Evidence on the association between raw cow*s milk consumption and immunity is restricted to early-life exposure. Due to its microbiological hazard, raw cow*s milk consumption is not recommended. It is estimated that 30% of dairy farmers does drink raw cow*s milk on a regular basis, making them a suitable study population to study the association between raw milk consumption and the occurrence of various diseases. To be able to conduct a future RCT, observational data as well as data on the difference and variance of inflammatory markers in those with high versus low raw cow*s milk consumption is required. This essential information will be gathered in the current study.

Study objective

The main aim of the proposed study is to 1) assess the habitual consumption of raw cow*s milk among a large population of adult dairy farmers; 2) assess the association between raw cow*s milk consumption and inflammation-related, auto-immune and infectious disease prevalence and incidence, and 3) explore the differences and associated variances in the age-related inflammatory markers IL-6, CRP, and sVCAM in serum between elderly dairy farmers that consume raw cow*s milk versus those that consume ultra-high-temperature (UHT)-processed cow*s milk instead. If a link between raw cow*s milk consumption and inflammation exists, novel dietary strategies based on minimal processing of milk may become reality and will contribute to reduce the burden of inflammation-related, auto-immune, and infectious diseases.

Study design

This study will consist of a prospective cohort study with baseline cross-sectional data and a feasibility study for a future RCT study to enable the design of a randomized controlled trial evaluating the effect of minimally processed cow*s milk consumption on inflammatory markers. From the almost 18.000 dairy farmers associated with Friesland Campina, participants will be recruited for the cohort study, in which they are asked to fill out several questionnaires assessing habitual dietary intake, disease prevalence, drug use, history of education, smoking status, and physical activity. For the prospective study, subjects will be asked to fill out the questionnaires every 2 years, with a total follow-up for at least 10 years.

While recruiting participants for the cohort study, 60 elderly subjects will be recruited living in the vicinity of Wageningen for the feasibility study: 30 consumers of raw cow*s milk and 30 consumers of UHT-processed cow*s milk. Thirty ml of blood will be drawn. Levels of the inflammatory markers IL-6, CRP,

and sVCAM will be analysed and compared between groups.

Funding is currently available for recruitment, baseline assessments and cross-sectional data-analyses of the cohort study and recruitment, blood collection, assessment of serum levels of IL-6, CRP and sVCAM of the 60 elderly farmers recruited for the feasibility study. For follow-up of the cohort and, ultimately, for conducting an RCT with minimally processed cow*s milk, additional funding will be sought.

Study burden and risks

Subjects fill out multiple questionnaires, and for half a year before filling out the questionnaires, subjects will keep track of how often they had an infectious disease (like flu or nasal cold). 30 ml of blood will be drawn from sixty elderly subjects in the region. The study subjects will have no direct benefit from the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- At least 18 years of age
- Speaks Dutch
- Works or lives at a dairy farm

For the pilot study: at least 60 years of age

Exclusion criteria

- A self-reported milk allergy or sensitivity to dairy ingredients
- Mental status that is incompatible with the proper conduct of the study
- Personnel of FrieslandCampina or Wageningen University & Research, department
- of Cell Biology and Immunology or Human Nutrition and Health

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	20-04-2022
Enrollment:	5400
Туре:	Actual

Ethics review

Approved WMO	
Date:	07-06-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	11-05-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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 NL75622.081.20