MOSAIC-2 Study: MOdel to Study upper Airway Immunity upon Cholera vaccination

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To investigate whether raw milk, pasteurized milk or ultra-heat treated (UHT) milk is able to enhance the systemic immune response as induced by oral cholera vaccination, in comparison to regular vaccination. Oral vaccination can also induce an...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43345

Source
ToetsingOnline

Brief title
MOSAIC-2

Condition

- Other condition
- Hepatobiliary neoplasms malignant and unspecified
- Respiratory tract infections

Synonym
(upper) airway infection, (upper) respiratory tract infection

Health condition

respons van immuunsysteem op vaccinatie-challenge

Research involving

Human

Sponsors and support

Primary sponsor: FrieslandCampina Nederland BV
Source(s) of monetary or material Support: FrieslandCampina Nederland BV

Intervention

Keyword: IgA, immunity, milk, vaccination

Outcome measures

Primary outcome

Primary outcome is the increase in vaccine-specific secretory IgA levels

detectable in serum at day 14 after vaccination.

Secondary outcome

Secondary outcomes are vaccine-specific secretory IgA (and IgG) levels in

saliva, nasal wash and feces.

Study description

Background summary

Oral vaccination is known to induce a systemic immune response as well as a weak immune response in the upper airways, and can therefore serve as a model to study systemic and upper airway immunity. The oral cholera vaccine Dukoral® was chosen as model vaccine. The kinetics of the immune response and the interaction with a raw milk matrix have been evaluated in a previous, pilot study (NL49042.081.14). Based on the outcomes of this pilot, in this study oral cholera vaccination will be applied to study the support of (upper airway) immunity by raw milk, compared to heat-treated milk. The study design has been optimised based on previous results: study duration is extended and sample size is based on relevant change and known variation in the primary outcome parameters.

Study objective

To investigate whether raw milk, pasteurized milk or ultra-heat treated (UHT)

milk is able to enhance the systemic immune response as induced by oral cholera vaccination, in comparison to regular vaccination. Oral vaccination can also induce an immune response in the upper airways. Therefore, the effect of milk on the upper airway response after vaccination will also be analysed.

Study design

Four groups of 27 healthy adult volunteers (total n=108) will be vaccinated with the oral cholera vaccine Dukoral®. The vaccine is given on day 0 and day 14 of the study. One group will receive the vaccine in the regular sodium carbonate buffer. The other groups will receive the vaccine in a matrix of raw milk, UHT milk or pasteurized milk, respectively. At baseline, and 14, 28 and 42 days after start of the vaccination, the immune response will be measured in blood, saliva, nasal wash and feces.

Intervention

1) Raw milk, obtained from farms that comply to the high quality requirements for production of raw milk, and that has been screened according to the safety criteria for raw milk (a.o. presence of specific pathogens); 2) commercially available full-fat UHT milk; 3) commercially available full-fat pasteurized milk

Study burden and risks

The participants will visit the study location once for screening and 4 times for vaccination and/or sample collection. At those 4 time points, 40-60 mL of blood will be drawn (total amount 240 mL). At all time points, a nasal wash will be performed. At 4 time points, saliva and fecal samples will be collected. At 2 time points, the participants will receive a dosage of the vaccine.
Dukoral® is a registered vaccine, consisting of heat-killed and formalin-killed Vibrio cholerae plus recombinant cholera toxin subunit B. The vaccine can be safely used for adults and for children above the age of 2 yr. The vaccination has a low risk of side effects, and the side effects are mainly mild. One group will receive the vaccine in a matrix of raw milk. Raw milk has a potential risk of containing pathogens that can result in gastrointestinal disease. By selecting farms that comply to strict quality criteria, and by screening the milk for specific pathogens, the risk of subsequent infection is considered very limited. In the previous MOSAIC study (NL49042.081.14) no adverse events were observed related to the consumption of raw milk.
Two groups will receive the vaccine in a matrix of full-fat pasteurized or UHT milk. This does not results in extra risks.
Side effects occurring during the study will be registered by a short daily online survey. If serious side effects occur, the study doctor will be consulted.

The study participants will have no direct benefit from the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age 18-50yr
Male or female
Signed informed consent
Willing to stop blood donation during the study period

Exclusion criteria

Currently participating in another clinical trial
Previous cholera or E. coli vaccination
Tonsillectomy
Acute gastroenteritis in the past 2 months
use of antibodies in the past 2 months
Hypersensitivity to the vaccine, to formaldehyde or to any of the excipients (sodium salts)
Pregnancy or lactating (pregnancy test will be made available in case of doubt on vaccination days)
Not willing to drink raw milk
Not willing to adhere to diet restrictions during the study
Allergy to milk or lactose intolerant
Disease of GI tract, liver, gall bladder, kidneys, thyroid gland
Immune-compromised
Use of immune-suppressive drugs
Drug abuse, and not willing to stop this during the study
Excessive alcohol usage (men: >4 consumptions/day or >20 consumptions/week; women: >3 consumptions/day or >15 consumptions/week)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2016
Enrollment:	108
Type:	Actual

Ethics review

Approved WMO Date:	14-06-2016
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	ID
CCMO	NL56906.081.16