

# Tolerance of camel\*s milk and mare\*s milk in cow\*s milk protein allergy.

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Primary: To establish the tolerance of camel\*s milk and mare\*s milk in standardized food provocation tests in patients with double-blind placebo-controlled provocation (DBPCP) proven CMA  $\geq 3$  years of age. Secondary: To determine the minimum...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON39043

### Source

ToetsingOnline

### Brief title

The PAKA study.

### Condition

- Other condition

### Synonym

cow's milk allergy

### Health condition

voedselallergiën

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Benemel en Smits Kamelenmelk

**Source(s) of monetary or material Support:** Benemel;Smits Kamelenmelk;Syntens;Eureka;5-sterrenregio.

## Intervention

**Keyword:** Allergy, Camel's milk, Cow's milk, Mare's milk

## Outcome measures

### Primary outcome

Tolerance of camel\*s and mare\*s milk, as determined by provocation tests.

### Secondary outcome

1. the minimum eliciting dose of camel\*s milk and mare\*s milk in CMA patients who do not tolerate these milk(s) in standardized food provocation tests; 2. medium-term (four weeks) tolerance of camel\*s and/or mare\*s milk in those participants who were negative in the provocation tests; 3. long-term (6-12 months) tolerance of camel\*s and/or mare\*s milk in those participants who were advised they could go on consuming the milk(s); 4. titer and affinity of specific IgE in serum to cow\*s milk, camel\*s milk and mare\*s milk at the start of the study, and after four weeks of daily consumption of camel\*s and/or mare\*s milk; 5. the patients'experience with the consumption of camel's milk and mare's milk.

## Study description

### Background summary

Cow\*s milk protein allergy (CMA) is a common problem in young infants, but can also occur in older children and adults. Camel\*s milk and mare\*s milk proteins

differ considerably from those in cow's milk. Therefore they might be tolerated by patients with CMA, as has been shown in a few small studies.

## **Study objective**

Primary: To establish the tolerance of camel's milk and mare's milk in standardized food provocation tests in patients with double-blind placebo-controlled provocation (DBPCP) proven CMA  $\geq 3$  years of age. Secondary: To determine the minimum eliciting dose of camel's milk and mare's milk in CMA patients who do not tolerate these milk(s) in standardized food provocation tests; to investigate medium-term (4 weeks) and long-term (6-12 months) tolerance of camel's milk and mare's milk in CMA patients who do tolerate these milk(s) in standardized food provocation tests; to determine the titer and affinity of specific IgE to cow's milk, and the titer and affinity of specific IgE to camel's milk and mare's milk before introduction, and after 4 weeks of daily ingestion in the CMA patients who tolerate these milk(s) in standardized food provocation tests. The patients' experience with the consumption of these milks will be analysed in a short questionnaire.

## **Study design**

Randomized cross-over intervention trial.

## **Intervention**

Participants are randomized to receive increasing doses of either camel's milk or mare's milk in a standardized provocation test. One to four weeks later the participants who first received camel's milk, receive mare's milk, or the reverse. Participants who did not show allergic reactions to one milk will consume that milk daily for four weeks; participants who did not show allergic reactions to both milks will be randomized to receive camel's milk or mare's milk daily during four weeks, and the other milk during the four weeks thereafter. If no allergic symptoms occur during those four weeks, participants are advised that they can go on consuming this milk if they want to. At 6-12 months after study entry, participants who had been advised they could go on consuming one or both milks will be asked to answer a questionnaire on their experiences with these milks.

## **Study burden and risks**

Patients who should be considered as high-risk for DBPCP are excluded from participation. A maximum of five study visits take place (at inclusion, during the 2 provocation tests for camel's milk and mare's milk in the day care hospital, and - if applicable - after the four weeks of daily camel's milk and mare's milk consumption). Venepuncture is performed 0-3 times, depending on the presence of left-over material before the study, and the reactions in the

provocation tests (when both are positive, the study stops). A diary is completed daily to record symptoms during 2-10 weeks.

## Contacts

### Public

Benemel en Smits Kamelenmelk

Benemel: Graafsebaan 3. Smits Kamelenmelk: Werstkant 16. 0

Benemel: 5411RE Zeeland. Smits Kamelenmelk: 5258 TC Berlicum. 0  
NL

### Scientific

Benemel en Smits Kamelenmelk

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

### Inclusion criteria

Cow's milk protein allergy proven by double-blind placebo-controlled provocation;  $\geq 3$  years of age.

## Exclusion criteria

Experienced a life-threatening reaction to a food allergen; instable asthma.

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2012
Enrollment:	31
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	20-02-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	06-06-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	13-01-2014
Application type:	Amendment

## 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	NL38223.028.11