Effect of colostrum on immune function after intense strenuous exercise in well-trained cyclists.

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The primary objective of this study is to evaluate the effect of colostrum supplementation on the immune response after intense strenuous exercise.The secondary objective is to study the effect of intense strenuous exercise - and its possible...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immune disorders NEC
Study type	Interventional

Summary

ID

NL-OMON32615

Source
ToetsingOnline

Brief title
Colostrum, exercise and immune function

Condition

- Immune disorders NEC
- Hepatobiliary neoplasms malignant and unspecified

Synonym
common cold, upper respiratory tract infection (URTI)

Research involving
Human

Sponsors and support

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

VOF

Intervention

Keyword: colostrum, endocannabinoids, exercise, immune function

Outcome measures

Primary outcome

The immune function will be assessed by measuring changes in several markers, i.e. salivary IgA level, plasma immunoglobulins and cytokines, number of lymphocytes, neutrophils and natural killer cells and plasma cortisol concentration. In addition, in vitro cell proliferation, cytokine production and apoptosis in peripheral blood mononuclear cells (PBMCs) will be measured.

Secondary outcome

Changes in circulating metabolites and endocannabinoids serve as secundary study parameters.

Study description

Background summary

After prolonged, strenuous physical exercise the immune function is impaired for ~3 to 24 hours (Gleeson, 2007). This causes an *open window* in which a subject is more susceptible for infections, especially upper respiratory tract infections (URTI). Bovine colostrum is proposed to counteract this exercise-induced reduction in immune function. However scientific evidence is inconclusive so far.

Study objective

The primary objective of this study is to evaluate the effect of colostrum supplementation on the immune response after intense strenuous exercise. The secondary objective is to study the effect of intense strenuous exercise - and its possible modulation by colostrum - on plasma endocannabinoid levels.

Study design

A cross-over intervention study with a randomized, double-blind, placebo controlled design.

Intervention

Subjects will either start with colostrum supplementation or placebo (skimmed milk powder). After a wash out period of 3 weeks the other supplement will be taken. The colostrum is 12h bovine colostrum supplied by Arts Food Products. The placebo is skimmed milk powder. From both, the colostrum and the placebo 12.5 gram twice daily will be consumed. After each 10-day period of supplementation, subjects will undergo an intense exercise protocol to evaluate the effect of exercise on immune function

Study burden and risks

Subjects will undergo an exercise protocol twice, once with colostrum and once with a placebo. The exercise protocol consists of three parts: 1) a maximal aerobic capacity test, 2) a glycogen depletion part and 3) 1.5h of continuous cycling. Part 1 and 2 will take place in the evening and part 3 will be done the next morning. The exercise protocol is severe and is designed to stress the immune system. The study population (well-trained cyclists) is used to this kind of exercise - the requested amount and intensity of physical activity does not exceed their training routine. Therefore, they should be able to complete the protocol without any problems. Any sign of - gastro-intestinal or respiratory tract - infection one month before and during the study will be monitored, and adequate steps will be taken, if necessary.
Blood and saliva will be collected at 4 time-points throughout each experimental period within a 36-hour time frame. Total blood sampling is ~100 mL per experimental period (200 mL for the entire study). Blood sampling can give some discomfort and occasionally result in a local haematoma.
Subjects are asked to hold an illness log, a dietary log and an exercise log during the whole experiment. Dietary guidelines are provided during the run-in and experimental period.
The supplement used in this study, i.e. colostrum is not expected to have any serious health effects. Participation in this study does not result in a direct health benefit. If a positive effect of colostrum supplementation is found, this could eventually result in the use of colostrum in the nutritional routine of endurance athletes to prevent symptoms of URTI and other infections.

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

- Male cyclists/triathletes with at least 2 years of cycling experience.
- Cycling at least 3 times a week during peak season.
- 18 - 35 years old.
- Body mass index (BMI) 20 - 25 kg/m2.

Exclusion criteria

- Known symptoms of milk allergy.
- Known symptoms of immune disease.
- Symptoms of infections during the last month before the start of the experiment.
- Smoking.
- Use of more than 2 alcoholic consumptions per day during the last 2 weeks before the start of the experiment and during the experiment itself.
- Use of drugs.
- Use of colostrum during the last month before the start of the experiment.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2008
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	31-10-2008
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	NL24484.081.08