Human Exposure to RhinOvirus * Effect of a plant-based polysaccharide food supplement on upper respiratory symptoms

Published: 19-10-2017
Last updated: 12-04-2024

This study is designed to test if consumption of a vegetable extract as a food ingredient improves resistance to an experimental respiratory tract infection with RV16 in healthy volunteers.Primary Objective: * To test and quantify the effect of the…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON44493

Source
ToetsingOnline

Brief title
HERO Reborn

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
acute rhinitis, common cold

Research involving
Human

Sponsors and support

Primary sponsor: Nutrileads B.V.
Source(s) of monetary or material Support: Nutrileads BV en Europese Unie (EFRO subsidie)

Intervention

Keyword: anti-viral response, common cold, rhinovirus infection, Vegetable extract

Outcome measures

Primary outcome

* Severity of symptoms using validated WURSS-21 questionnaire on day -1 to 13

following experimental infection

* Viral titer in nasal lavage

Secondary outcome

* Duration of infection based on combination of RV16 viral titers, symptoms and

elevated IL8 in nasal lavage

* Change in IL-8 and IP10 levels in nasal lavage

* Increase in phagocyte activity between baseline and day before infection

Study description

Background summary

Common cold symptoms are unpleasant, dangerous for people with a compromised immune system, and have a significant economic impact, accounting for millions of workdays missed annually, worldwide. Enhancing resistance to common cold infections will generally contribute to wellbeing. In recent proof of concept studies, a polysaccharide component of certain food crops has been shown to modulate immune response in a way that suggests it may be effective in supporting protection against infections.The promising outcomes of these earlier studies need to be confirmed in a randomized controlled trial, testing the effect on symptoms in otherwise healthy subjects.

Study objective

This study is designed to test if consumption of a vegetable extract as a food ingredient improves resistance to an experimental respiratory tract infection with RV16 in healthy volunteers.
Primary Objective:
* To test and quantify the effect of the vegetable extract on reduction of severity of common cold symptoms after experimental infection with RV16, as assessed by the WURSS-21 questionnaire over 13 days following infection
* To test and quantify the effect of a vegetable extract on reduction of viral load in nasal lavage, after experimental infection with RV16, over 13 days following infection

Secondary Objectives:
* To test the effect of a vegetable extract on duration of infection based on a combination of RV16 viral titers, symptoms and elevated IL-8 in nasal lavage
* To test the effect of a vegetable extract on change in IL-8 and IP10 levels and cell differentials in nasal lavage over 13 days following infection, compared to pre-infection levels
* To test the effect of a vegetable extract on the increase in phagocyte activity between baseline and the day before experimental infection

Study design

Randomized, double-blind, placebo-controlled trial with three parallel arms, in which all groups will be challenged with a low dose of human rhinovirus-16 (HRV-16).

Intervention

Three groups:
placebo
low dose of a vegetable extract
high dose of a vegetable extract

Study burden and risks

Study participants will have no direct benefit from participating. The main burden for participants is that they will suffer from a common cold episode and will have to visit the AMC hospital 10 times over a period of 15 weeks.
The RV16 infection protocol has often been used to challenge healthy individuals, mild (allergic) asthmatics and COPD patients. The rationale for using RV16 is that this rhinovirus strain causes mild common cold symptoms as compared to other rhinovirus strains. In addition, RV16 is not considered to be very contagious. No adverse effects of using RV16 in healthy individuals and patients have been reported.

Blood samples will be collected 8 times; a nasal lavage will be performed on 6 occasions. Questionnaires have to be completed on 21 days during the study. Participants will experience the physical discomfort associated with a common cold episode. The health risks associated with participation are considered to be minimal.

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

Healthy adults (men and women) from the general population
1. Age *18 and *65 years of age
2. Sero-negative (* 1:6) to HRV-16 at screening
3. Body mass index (BMI) * 18.5 and * 30.0 kg/m2
4. Healthy (assessed by study physician, based on medical history and used medication as

provided by the participant)
5. Willingness to comply with study procedures
6. Having a GP
7. Signed informed consent

Exclusion criteria

* History of hay fever and rhino-sinusitis
* History of asthma or COPD
* History of food allergy or food intolerance
* Underlying pulmonary, cardiovascular or auto-immune disease
Use of statins
* History of significant medical or psychiatric disease, at the discretion of the study physician
* Pregnant or intending to become pregnant during the study period and lactating women
* Frequent contact with elderly, immune deficient or severe asthma/COPD patients or children under the age of 2 years during the course of the trial
* NutriLeads or AMC employee of departments of Respiratory Medicine and Experimental Immunology
* Current or ex-smoker (last half year)
* Consumption of > 14 alcoholic units in a typical week (females) or > 21 alcoholic units in a typical week (males)
* Strenuous exercise (> 10 hrs/wk)
* Any other medication at the discretion of the study physician
* Recreational drug abuse
* Language limitations regarding interviews and questionnaires
* Volunteers who share the same house(hold)
* Currently participating in another clinical trial
* Reported, unexplainable weight loss or gain >3 kg in the last month before screening visit
* Night shift worker

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2017
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO Date:	19-10-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL62623.018.17