RUDOLPH Study; Changes in nasal microbiota and concurrent nose soreness associated with common cold infection * a pilot using the HRV-16 challenge model in healthy subjects

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Primary Objective: * Explore association between nasal microbiota composition and occurrence of nose redness and soreness during rhinovirus infectionSecondary Objectives: * Explore the potential of the HRV-16 challenge model to produce covariates of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON45430

Source
ToetsingOnline

Brief title
RUDOLPH Study

Condition

- Respiratory tract infections
- Epidermal and dermal conditions

Synonym
nasolabial erythema associated with common cold; sore nose

Research involving
Human

Sponsors and support

Primary sponsor: Kimberly-Clark Corporation
Source(s) of monetary or material Support: industry

Intervention

Keyword: nasal microbiota, nasolabial erythema, rhinovirus infection

Outcome measures

Primary outcome

The microbiota composition of the nasal cavity, anterior nares and nasolabial

skin, and shifts in composition during the course of experimental RV16

infection in subjects with occurrence of nasolabial erythema and nose soreness

Secondary outcome

* Erythema of the nasolabial area

* Nose soreness

* Common cold symptoms

* Biomarkers of inflammation and skin barrier function

Study description

Background summary

Diminished skin barrier function can predispose skin to inflammatory events. Irritation of nasolabial skin and reduced skin barrier function occurs during common cold episodes. Microbiota composition and shifts in composition that occur in the nasal cavity during a common cold episode may affect the composition of nasal secretions. This may, directly, or via the route of modulating local microbiota composition on the nasolabial skin, affect the susceptibility of individuals to irritation and inflammation of the nasolabial skin. This pilot study will utilize the experimental rhinovirus infection model to study changes in skin microbiota in relation to skin erythema and soreness.

Study objective

Primary Objective:
* Explore association between nasal microbiota composition and occurrence of nose redness and soreness during rhinovirus infection
Secondary Objectives:
* Explore the potential of the HRV-16 challenge model to produce covariates of nasolabial redness and soreness associated with common cold.
* Explore association between nasal microbiota composition obtained by nasal wash (nasal cavity) and nasal swabs (anterior nares) and skin microbiota obtained by nasolabial skin swabs, before and during rhinovirus infection
* Explore changes in biomarkers of inflammation and skin barrier function during the course of a rhinovirus infection
* Explore association between biomarkers of inflammation and skin barrier function and occurrence of nose redness and soreness during rhinovirus infection

Study design

non-randomized pilot study of a nasal rhinovirus16 (RV16) challenge

Intervention

There are no (pharmacological or other) treatments being studied. This study involves a nasal RV16 challenge in all subjects.

Study burden and risks

Study participants will have no direct benefit from participating. The main burden for participants will be that they will suffer from a common cold episode and will have to visit the AMC hospital seven times.
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 considered to be not very contagious. No adverse effects of using RV16 in healthy individuals and patients have been reported.
Two small blood samples will be collected, one at the start and one at the end of the study. A nasal lavage will be performed on 6 occasions; skin swabs will be performed on 7 occasions during a visit, and 3 times by the participants themselves, at home. Questionnaires have to be completed on 16 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 men or women
- Age *18 and *50 years of age
- Self reported proneness to developing symptoms of nose redness and/or soreness.
- Fitzpatrick skintypes I, II or III
- Sero-negative (< 1:6) to HRV-16 at screening (shortly before inclusion)
- Willing to adhere to the study procedures

Exclusion criteria

- Pregnancy or lactating
- History of pre-existent lung disease, including asthma

- Confirmed or self-reported allergic rhinitis
- Use of anti-inflammatory medication (i.e. nasal steroids and topical steroids in the nasolabial area) or medication targeted at treatment of nose and/or lung problems. NSAIDS like ibuprophen, etc, are acceptable
- Use of antibiotics (oral/topical, within 3 months prior to the start of the trial)
- Use of anti-histamines or other non-prescription cold medicines
- Use of alcohol > 5/day or >20/wk
- Use of any drugs
- Current smoker, or smoked in past 12 months, or more than 5 pack-year history. Smoking includes cigars, marijuana and electronic cigarettes
- More than 3 nosebleeds per month
- History of nasal or otologic surgery
- Febrile illness or a common cold within six weeks before the HRV challenge
- Presence of atopic dermatitis, rosacea, psoriasis, and/or eczema on or near the nose.
- Recent surgery within the past 3 months
- Immunocompromised condition or chronic disease the investigator feels is significant
- Frequent contact with elderly or children under the age of 2 years during the course of the trial
- Currently participating in another clinical trial

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2017
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	01-02-2017
Application type:	First submission
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	NL60212.018.16