Testing virucidal efficacy of alcohol based hand disinfectant and the transfer ratio of virus from hand to environmental fomites.

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

Summary

ID

NL-OMON37609

Source
ToetsingOnline

Brief title
Testing virucidal efficacy hand disinfectant

Condition

- Other condition

Synonym
not applicable

Health condition

het gaat niet om aandoeningen; het gaat om de activiteit van handdesinfectiemiddelen tegen norovirussen, op kunstmatig besmette vingertoppen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: virucidal hand disinfectant transfer

Outcome measures

Primary outcome

The counts of noroviruses on finger tips, direct after application and after

the use of 'hand rubs' or the washing of hands with soap and water give an

indication if there is a difference between both methods or not.

Secondary outcome

na

Study description

Background summary

The most important means of preventing norovirus transmission and infection is exercising frequent and appropriate hand washing. Alcohol-based hand sanitizers (>=62% ethanol) may be helpful as an adjunct method of hand hygiene, but should not replace washing with soap and water.
Evidence for efficacy against norovirus is usually based on studies using murine norovirus (MNV) as a surrogate. However, MNV and human norovirus (HNV) exhibit different physiochemical properties and it is unclear whether inactivation of MNV reflects efficacy against norovirus.
In the study described in this proposal the virucidal activity of two alcohol based hand disinfectants will be tested on MNV, a surrogate for HNV, and on two types of HNV. The results will be compared with traditional washing with water and soap. The hypothesis is that alcohol based hand disinfectants are less effective in inactivating HNV than the removal of norovirus obtained by proper hand washing. If this is true, avcices will be formulated so that appropriate

hygiene measures can be taken during outbreaks.

Furthermore, the transmission experiments described in the study will give information about the transfer of noroviruses from contaminated surfaces and food products to finger pads and from contaminated finger pads to surfaces and food products. Results will lead to a better understanding of the way of transmission after repeated contacts.

Study objective

The primary objective of this study is to test the virucidal efficacy of two alcohol based hand disinfectants (according prEN 12791) against murine norovirus 1 (MNV1) and human noroviruses (G1.4 and GII.4) on artificially contaminated hands. The results obtained will be compared to the effect of hand washing using soap and rinsing water, followed by drying with disposable towels.

The secondary objective is to quantify the decrease in transmission from artificially contaminated hands (both before and after treatment with an alcohol rub) to inanimate surfaces and food products.

Study design

see protocol

Intervention

Hands from test persons, where part of the finger tips are artificially contaminated with norovirus will be treated with 'hand rubs' (according to the manufacturer's instructions). Traditional handwashing with soap and water is used as control.

Study burden and risks

The burden for test persons is not quite high. After artificial contamination of their finger tips with norovirus they have to perform some actions: pressing finger tips on surfaces, using hand rubs and washing their hands in a traditional way with soap and water. Finally, a disinfectian step to inactivate the viruses.
During the session the investigator and assistant talk with the test person. In between 'commands'are given as described above.

Contacts

Public

Wageningen Universiteit

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Ten persons, employees and/or students, (no cuts and/or abrasions on fingers and not pregnant) will be randomly selected from the persons working in the WUR buildings located at the Dreijen (Wageningen) that answered the inviting email. Both males and females will be included. A form with questions about dermatological disorders will be used for inclusion/exclusion. The persons mentioned under C8, Wilma Hazeleger and Rijkelt Beumer, will be responsible for inclusion/exclusion. Test persons will be checked about 15 min before start of the experiments on dermatological disorders. A final check just before the start of the experiments (within 5 min) will be done by the researcher (Era Tuladhar).

Exclusion criteria

dermatological disorders: cuts, lesions, infections, eczema, psoriasis, and being pregnant

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-07-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	29-06-2012
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	NL39407.081.12