ROLE OF SKIN ABSORPTION ON UPAKE OF ALCOHOL IN HAND DISINFECTION

Published: 28-03-2023
Last updated: 08-02-2025

Determination of the contribution of skin absorption relative to inhalation as the route of uptake of alcohol following topical application of ABHR for hygienic disinfection in a controlled laboratory setting to support an improved risk assessment

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON53379

Source
ToetsingOnline

Brief title
ADLAN

Condition

- Other condition

Synonym
not applicable

Health condition

Er wordt geen aandoening onderzocht omdat het om een kinetiek studie gaat

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Sociaal Fonds voor de Kennissector (SoFoKleS)

Intervention

Keyword: dermal, dsinfection, ethanol, kinetics

Outcome measures

Primary outcome

- Blood concentration of alcohol and alcohol-d6

- Exhaled air concentration of alcohol and alcohol-d6

Secondary outcome

- Amount of hand disinfection product applied

- Ethanol concentration in ambient air

- Room size and free air volume

- Air exchange rate of the room ventilation system

- Air concentration of ethanol

- Trans-epidermal water loss (TEWL), skin hydration and skin pH

- Chronic hand dermatitis according to severty scale Coenraads et al 2005

Study description

Background summary

The use of alcohol-based hand rubs (ABHR) for hygienic disinfection by healthcare workers leads to uptake by inhalation and presumably also by skin absorption. A safety evaluation addressing the risk of low exposures over a long-term exposure is incomplete due to the lack of human data. We propose a volunteer study in a controlled laboratory environment to study the kinetics of the uptake of alcohol by inhalation and dermal absorption to support the

calibration of a physiology-based pharmacokinetic (PBK) model. This model will then be used to support exposure assessment by human biomonitoring. Forthcoming data will be used for the human risk assessment of professional ABHR practice.

Study objective

Determination of the contribution of skin absorption relative to inhalation as the route of uptake of alcohol following topical application of ABHR for hygienic disinfection in a controlled laboratory setting to support an improved risk assessment

Study design

Intervention study using Steriliium med as a commonly used product for hygienic disinfection with 85% alcohol in a controlled laboratory setting. This product will be doped with 1% deuterated alcohol (alcohol-d6) to make the distinction between alcohol from the hand disinfection product and other sources.

Study burden and risks

Burden and risk for the study participants:
- Participants are asked to avoid certain food/beverages that contain ethanol and/or lead to increased endogenous production for a period of 24 h prior to the study.
- Complete a questionnaire related to job title/tasks, use of food/beverages and personal care products with a focus on skin care
- Four one-day visits to the lab for the ABHR application. The lab visits are planned with a delay of at least 24 h wash-out period
- On each of four days a series of 10 blood samples of 3 mL over a period of 4 h hours
- On each of four days a series of 10 end-exhaled air over a period of 4 hours
- Blood collection by venepuncture may cause pain and/or localised haemorrhage
- Skin contact may cause mild irritation. Irritation of the eyes will be prevented by wearing of goggles.
- This exposure to the hand disinfection product is not expected to cause any long-term risk of significance

Contacts

Public
Radboud Universiteit Nijmegen

Heyendaalseweg 135
Nijmegen 6525 AJ

NL
Scientific
Radboud Universiteit Nijmegen

Heyendaalseweg 135
Nijmegen 6525 AJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Caucasian descent
- Employment in the healthcare (hospital, GGD or similar)
- Applying >25 ABHR/work shift for at least 3 full shifts/week
- 18-55y

Exclusion criteria

- Skin disease
- Liver disease
- Pregnancy
- Breastfeeding

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2023
Enrollment:	6
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-03-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL83686.091.23