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Seeking clearer recommendations for hand hygiene in communities facing Ebola: a randomized trial investigating the impact of six handwashing methods on skin irritation and dermatitis

Submission date
26/01/2016

Recruitment status
No longer recruiting

Registration date
27/01/2016

Overall study status
Completed

Last Edited
16/02/2023

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Healthcare workers worldwide often complain of irritation and dryness of the skin on hands as a result of the frequent handwashing necessary to keep both themselves and their patients safe, and there is a lack of good evidence to make recommendations about which handwashing methods are best. These concerns are especially pronounced in a setting where there is a high risk of spreading infection, for example, Ebola treatment centers, where any damage to skin could increase the risk of transmission. Healthcare workers and international emergency responders are seeking clearer handwashing guidelines, especially in the wake of the recent Ebola crisis in West Africa. The goal of this study is to compare the impact of different hand washing methods commonly used in healthcare settings on the development of irritant hand dermatitis to provide evidence from a controlled environment on the impact of these handwashing methods on skin health and comfort.

Who can participate?
Healthy volunteers (men and women) between the ages of 18 and 65.

What does the study involve?
Subjects will be randomly assigned to one of six groups. Those in group 1 are asked to wash their hands with soap and water ten times a day for 28 days. Those in group 2 are asked to use an alcohol-based hand sanitizer. Those in group 3 are asked to wash their hands in 0.05% calcium hypochlorite.Those in group 4 are asked to wash their hands in 0.05% sodium dichloroisocyanurate. Those in group 5 are asked to wash their hands in 0.05% sodium hypochlorite made from commercially available stock solution. Those in group 6 are asked to wash their hands in 0.05% sodium hypochlorite made using an electrochlorinator. During this time participants attend the Tufts University Medford campus to be monitored daily for discomfort or hand irritation.

What are the possible benefits and risks of participating?
Participants are not expected to experience a direct benefit from the study. The study carries with it a mild risk of development of dermatitis, no greater than the risk of frequent (but within normal) handwashing in daily life or work. Subjects may also find the time required to pick up new handwashing materials each day poses a burden.

Where is the study run from?
Tufts University, Department of Civil and Environmental Engineering (USA)

When is the study starting and how long is it expected to run for?
June 2015 to November 2015

Who is funding the study?
United States Agency for International Development

Who is the main contact?
Professor Daniele Lantagne
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
AID-OFDA-A-15-00026

Study information

Scientific Title
Comparison of soap, hand sanitizer, and 0.05% NaDCC, HTH, and NaOCl chlorine solutions in the development of dermatitis among healthy volunteers during frequent handwashing

Study objectives

We hypothesize that the development of dermatitis on the hands among subjects will vary depending on the substance used for handwashing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board at Tufts Medical Center and Tufts University Health Sciences Campus, 08/09/2015, ref: #11818

Study design
Single-centre interventional trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Irritant contact dermatitis is a condition of skin inflammation and skin barrier disruption that can cause transepidermal water loss, itching, redness, swelling, and an increase in disease transmission risk when irritating substances cause dehydration of the stratum corneum.

Interventions
Subjects are randomly allocated to one of six arms. They are asked to wash their hands ten times per day with the handwashing method assigned to them. The handwashing methods are:
1. washing with soap and water
2. alcohol-based hand sanitizer
3. 0.05% calcium hypochlorite
4. 0.05% sodium dichloroisocyanurate
5. 0.05% sodium hypochlorite made from commercially available stock solution
6. 0.05% sodium hypochlorite made using an electrochlorinator

Intervention Type
Mixed

Primary outcome(s)
1. Hand Eczema Index Score (HECSI). The HECSI score is a measurement of skin irritation on hands composed of individual scores detailing the severity of nine different signs of irritation (itchiness, pain, redness, flaking, cracks in the skin, skin thickening, swelling, bumps, and blisters) on each part of the hands assigned by a trained researcher. A board-certified dermatologist will examine each subject to determine diagnosis of clinical dermatitis. HECSI score is measured at baseline and on each day of the 28 days of handwashing.
2. Clinical diagnosis of dermatitis. Dermatitis diagnosis takes place at endline, at the end of day 28 of handwashing.

Key secondary outcome(s))
1. Allergy patch testing. Patch testing is conducted to determine whether subjects have an allergy to any substance that might be a confounding factor if the subject develops irritation or

dermatitis and is done by placing a patch with small discs containing each substance used for handwashing on the upper back from 48hrs. Researchers then view the area for signs of allergy at 48hr, 96hrs, and 7 days.
2. Self-rated hand score. For the self-rated hand score subjects used a scale from 0-10 to self-rate the level of discomfort that they were currently experiencing on their hands along with nine different symptoms, including itchiness, pain, redness, flaking, cracks in the skin, skin thickening, swelling, bumps, and blisters.

Completion date
18/11/2015

Eligibility

Key inclusion criteria
Potential participants must be:
1. healthy volunteers
2. either gender
3. aged between 18-65
4. English-speaking

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
Potential participants must not:
1. have a history of dermatitis
2. be pregnant or trying to become pregnant
3. patch test positive for any study substance
4. have baseline skin abnormalities or open sores/cuts
5. work in a profession where hands are frequently wet or exposed to irritants
6. have mental health issues that may be triggered by a study related to hand hygiene

Date of first enrolment
11/09/2015

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
United States of America

Study participating centre
Tufts University, Department of Civil and Environmental Engineering
113 Anderson Hall
200 College Avenue
Medford, MA
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Sponsor information

Organisation
Tufts University

ROR
https://ror.org/05wvpxv85

Funder(s)

Funder type
Government

Funder Name
United States Agency for International Development

Alternative Name(s)
U.S. Agency for International Development, Agency for International Development, USAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/12/2016		Yes	No
Dataset	Data Dictionary. (XLSX)		16/02/2023	No	No
Dataset	Handwashing Data. (XLSX)		16/02/2023	No	No