

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	☐ Prospectively registered
		☐ Protocol
Registration date 27/01/2016	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 16/02/2023	Condition category Skin and Connective Tissue Diseases	☒ 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

Primary study design

Interventional

Study design

Single-centre interventional trial

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

United States of America

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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

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