

Hand washing study

Submission date 30/01/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/02/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/05/2019	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Streptococcus pneumonia (a type of bacteria) is a leading cause of morbidity and mortality worldwide, causing community acquired pneumonia (CAP), bacterial meningitis and bacteraemia. There is evidence to suggest that exposure of the hands to pathogens can lead to respiratory illnesses and therefore interventions such as handwashing is of significant global health importance. Our pilot study revealed that hand to nose transmission of S.pneumoniae is an important mechanism of bacterial transmission. This study tests the potential interventions to reduce hand to nose transmission i using hand washing intervention with the antibacterial soap Lifebuoy. The aim of this study is to assess the effect of hand washing with antibacterial soap on the rates of acquisition of pneumococcal colonisation following transmission from hand to nostrils.

Who can participate?

Adults aged 18 to 50 years old who are healthy.

What does the study involve?

Participants are randomly allocated to one of two groups. Participants receive a solution to decontaminate their hands before transmission and they are asked to follow the WHO hand rubbing protocol for 30 seconds. A droplet of bacterial broth is containing the desired dose of pneumococcus is placed on a certain part of the top of the hand. Those in the first group are asked to immediately rub the area of the hand exposed to the bacteria around their nose while sniffing, to try and get the bacteria to go into the nostril. Those in the second group are asked to wash their hands using antibacterial soap. Participants are followed up two days, six/seven days and 9/10 days after the exposure to try and detect the bacteria in their nose.

What are the possible benefits and risks of participating?

There are no direct benefits to the participants however, the research study may help us to improve medical care for others. Because the bacteria are alive, there is a very small risk of infection to participants or their close contacts. It is not expected for anyone to develop an infection but this is why participants are chosen carefully, and are monitored closely.

Where is the study run from?

Liverpool School of Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
September 2017 to June 2019

Who is funding the study?
Unilever (UK)

Who is the main contact?
Dr Caz Hales (Public)

Contact information

Type(s)
Public

Contact name
Dr Andrea Collins

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LSTM 17-077

Study information

Scientific Title
Hand to nose transmission of Streptococcus pneumoniae in healthy participants: Randomised control trial assessing the effect of hand washing on transmission

Study objectives
To assess the effect of hand washing with antibacterial soap on the nasopharyngeal colonisation acquisition rates following pneumococcal transmission from hand to nostrils.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Liverpool East Regional Ethics Committee, 05/01/2018, ref: 17/NW/0658

Study design

Single centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Pneumonia

Interventions

Healthy volunteers are randomly allocated to one of two groups. Randomisation is computer-generated and occurs in block sizes of 6. The clinical study team is un-blinded due to the nature of the intervention however, the study lab team who are processing samples and assessing for nasal colonisation are blinded until the end of the study.

Both groups use 70% ethanol solution to decontaminate hands before the transmission attempt. This is sprayed twice on to each of the palmer and dorsal surfaces, approximately 15-20 cm from the hands (total of 4mls of ethanol solution). Participants are then asked to follow WHO hand rubbing protocol for 30 seconds and allow hands to air dry.

Exposure Procedure: using a micropipette a droplet of bacterial broth containing the desired dose of pneumococcus is placed in the anatomical snuff box of one hand and spread around this area using the top of the micropipette.

Control group: Participants are then asked to immediately rub the area of hand that the bacterial stock had been exposed around their nasal orifice while sniffing, in an attempt to transmit part of the bacterial stock into both nares.

Intervention group: Participants are then asked to wash their hands using antibacterial soap. Hand washing protocol with interventional product:

1. The participant sparingly wets his/her contaminated hands by rapidly passing them under the tap
2. Study personnel dispense one pump of Lifebuoy soap into the palms of the subject's cupped hands
3. The participant washes/lathers both hands for 10 seconds \pm 1 second in a controlled fashion

4. The participant then rinses his/her hands for 30 seconds \pm 1 second under a stream of tap water. Following this, participants are asked to rub the area of hand that the bacterial stock had been exposed around their nasal orifice while sniffing, in an attempt to transmit part of the bacterial stock into both nares.

Post exposure- The participant is moved into a semi-recumbent position and remains so for 15 minutes. They are given a post-exposure advice sheet (including safety contact details), thermometer and a course of antibiotics to be taken if they become unwell or at the end of the trial if colonised at any time point.

Hand washing procedure post exposure: The World Health Organisations (WHO) guidelines on hand hygiene in health care is used to inform the hand washing protocols in this study. Gojo antimicrobial hand wash is used which is the hand wash used at the local NHS trust. Participants are asked to follow WHO hand washing protocol for 30-40 seconds. This includes initially wetting hands with water, wash for 30-40 seconds, turn off tap/faucet and dry hands thoroughly with single use towel using method that does not recontaminate hands.

Intervention Type

Other

Primary outcome measure

Detection of the exposed pneumococci is measured using classical culture methods at any time point from nasal wash recovered from participants at days 2, 6/7 and 9/10 after first pneumococcal exposure.

Secondary outcome measures

1. Occurrence of pneumococcal colonisation determined by the presence of pneumococcus in nasal wash is detected using classical microbiology at each time point post exposure at days 2, 6/7 and 9/10
2. The density of pneumococcal colonisation in nasal wash at each time point following pneumococcal exposure is detected using classical microbiology at days 2, 6/7 and 9/10
3. The area under the curve of pneumococcal colonisation density following pneumococcal exposure is detected using classical microbiology at days 2, 6/7 and 9/10
4. The duration of experimental pneumococcal colonisation determined by the last nasal wash following pneumococcal exposure in which pneumococcus is detected using classical microbiology
5. The occurrence of pneumococcal colonisation determined by the presence of pneumococcus in nasal wash at any time point post exposure up to and including day 9/10, detected using qPCR
6. Endpoints 1-4 detected using qPCR instead of classical microbiology methods

Overall study start date

01/09/2017

Completion date

07/06/2018

Eligibility

Key inclusion criteria

1. Adults aged 18-50 years - ages chosen to minimise the risk of pneumococcal infection, and to allow comparison with previously published experimental work done by our group

2. Fluent spoken English - to ensure a comprehensive understanding of the research project and their proposed involvement
3. Access to mobile telephone – to ensure safety and timely communication
4. Capacity to give informed consent

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

50 Years

Sex

Both

Target number of participants

170

Total final enrolment

179

Key exclusion criteria

1. Previous pneumococcal vaccination
2. History of major pneumococcal illness
3. Close physical contact with at risk individuals (children under 5 years of age, immunosuppressed adults, elderly, chronic ill health) at discretion of the study doctors and/or PI- minimise risk of pneumococcal transmission
4. Allergy to penicillin/amoxicillin and clarithromycin (or other macrolides)
5. Asthma (on regular medications) or chronic respiratory disease – confounding effect of medications such as corticosteroids, and propensity to infection
6. Any acute dermatological illness or skin injury affecting the hands or face at the discretion of the study doctors and/or PI- confounding effects of topical medications and propensity to infection
7. Taking daily medications that may affect the immune system e.g. steroids, steroid nasal spray, antibiotics and roacutane decision at the discretion of study doctors and PI
8. Current illness, acute illness within 3 days prior to exposure or antibiotic treatment within 2 weeks of exposure
9. Pregnancy - minimise risk of pneumococcal disease
10. Diagnosed as diabetic or any other illness that can affect patients' immune system- at the discretion of the study doctors and/or PI
11. Involved in another clinical trial unless observational or in follow-up (non-interventional) phase.
12. Have been involved in an EHPC clinical trial involving pneumococcal inoculation/exposure- at the discretion of study team depending on multiple factors attaining to previous study including previous pneumococcal vaccination, time since participation in the study and colonisation status in that study.

13. History of drug or alcohol abuse

14. History of Smoking

14.1. Current regular smoker (smokes daily/ smokes > 5 cigarettes per week) - minimise risk of pneumococcal disease

14.2. Recent smoker i.e. within the last 6 months - minimise risk of pneumococcal disease

14.3. Ex-smoker with a significant smoking history (>10 pack years) – minimise risk of pneumococcal disease

14.4. Unable to give fully informed consent

Date of first enrolment

05/02/2018

Date of final enrolment

07/06/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Liverpool School of Tropical Medicine

Accelerator Research clinic (ARC)

Liverpool

United Kingdom

L7 8XZ

Sponsor information

Organisation

Liverpool School of Tropical Medicine

Sponsor details

Research and Development

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England

United Kingdom

L3 5QA

Sponsor type

University/education

ROR

Funder(s)

Funder type

Industry

Funder Name

Unilever

Alternative Name(s)

Unilever Global, Unilever PLC, U

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

30/06/2020

Individual participant data (IPD) sharing plan

Participant level data will be held by the funders and all data enquiries should be made directly to them.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No