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Hand wash study

Submission date	Recruitment status	[_] Prospectively registered
14/03/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2018	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/11/2021	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Streptococcus pneumoniae 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 bacteria 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 method of bacterial transmission. We now plan to test potential interventions to reduce hand to nose transmission in this randomised control trial design using a hand washing intervention with the antibacterial soap Lifebuoy. The study aims to assess the effect of hand washing with antibacterial soap on the rates of transmission of bacteria from the hand to nose. 10% of the population carry the bacteria in their noses. We know that bacteria can be moved from the hand to the nose causing the spread of disease. We aim to demonstrate if a certain antibacterial soap can stop the bacteria passing from the hand to the nose.

Who can participate?
Healthy volunteers, male and female, age range 18-50

What does the study involve?
Healthy volunteers are randomly allocated to one of two groups; to immediately attempt transmission of the bacteria into their noses post exposure or hand washing with antibacterial soap prior to attempted transmission of the bacteria. All volunteers are exposed to the live bacteria on the back of their hands. Participants are asked to transmit the bacteria by rubbing their noses whilst sniffing. Volunteers are followed up for 2 weeks at clinic appointments where nasal wash samples are taken to see if the bacteria is present in their nose. At the end of the study, volunteers that still have the bacteria present in their nose will be given antibiotics to clear the bacteria.

Risks and Benefits:
The pneumococcal bacteria are live and therefore can pose the risk of a pneumococcal related infection. We have inoculated over 1000 healthy volunteers and patients combined without any serious adverse event related to the pneumococcal bacteria. There are no direct benefits to the participants. They will be compensated for their time and inconvenience.

Where is the study run from?
Liverpool School of Tropical Medicine: Accelerator Research Clinic (UK)

How long is the trial expected to run for?
October 2017 to May 2020

Who is the main contact?
1. Angela-Hyder Wright
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2. Dr Ryan Robinson
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Study website
www.lstmed.ac.uk/pneumoniavaccine

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17/NW/0658

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 evaluate if hand washing with antimicrobial soap affects hand to nose transmission of Streptococcus pneumoniae leading to nasal colonisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West Liverpool East, 21/12/2018, ref: 17/NW/0658

Study design
Randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Healthy volunteers. Prevention of respiratory infection.

Interventions
Healthy volunteers are randomised to wash their hands or not wash their hands after pneumococcal bacteria is placed on their hands. They are all then asked to transmit the bacteria by wiping their noses whilst sniffing up using the hand that has been exposed to the bacteria. The intervention appointment lasts for up to 1.5 hours. The volunteer is then followed up at day 2, 6/7 and 9/10 for a 15 minute appointment. Following day 9/10, volunteers are contacted if they need to take antibiotics.

The method of randomisation is sealed envelopes. The randomisation schedule has been produced by the statistician from the Tropical Clinical Trials Unit (tCTU). The envelopes were then made by 2 members of staff that are not involved in the clinical/ laboratory running of the study. The randomisation is 1:1 and occurs in blocks of 6. The envelope is opened on the day of exposure when the volunteer arrives and has passed all screening processes.

Intervention Type
Behavioural

Primary outcome measure
1. The presence of pneumococcal bacteria in the nose following exposure using classical microbiological methods. Nasal wash samples are taken pre-exposure, day 2, day 6/7 and day 9 /10. Pneumococcal bacteria serotype is confirmed by a commercially available latex agglutination kit.

Secondary outcome measures
1.The presence of pneumococcal bacteria in the nose following exposure using molecular methods (LytA PCR). Nasal wash samples are taken pre-exposure, day 2, day 6/7 and day 9/10.
2.The density of the bacteria in the nose following exposure.Density of bacteria is confirmed by counting the 6B pneumococcal colonies present in the nasal wash samples at day 2, 6/7 and 9/10.

Overall study start date
27/10/2017

Completion date
18/05/2020

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. Speak fluent 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 to allow 136 to complete the study

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 roacutanne 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
15.Current regular smoker (smokes daily/ smokes > 5 cigarettes per week) - minimise risk of pneumococcal disease
16.Recent smoker i.e. within the last 6 months - minimise risk of pneumococcal disease
17.Ex-smoker with a significant smoking history (>10 pack years) – minimise risk of pneumococcal disease
18.Unable to give fully informed consent

Date of first enrolment
30/01/2018

Date of final enrolment
30/12/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Liverpool School of Tropical Medicine: Accelerator Research Clinic
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Sponsor information

Organisation
Liverpool School of Tropical Medicine

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Sponsor type
University/education

ROR
https://ror.org/03svjbs84

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
18/08/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

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