ISRCTN12287744 https://doi.org/10.1186/ISRCTN12287744

Lifebuoy bar soap hand wash RCT

Submission date
10/04/2019

Recruitment status
No longer recruiting

Registration date
02/05/2019

Overall study status
Completed

Last Edited
29/01/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Pneumococcus bacteria can cause severe infection such as pneumonia, sepsis and meningitis particularly in
those with lower immunity, the very young and elderly. This bacteria is commonly present in the nose of healthy adults without any sign of illness (10%) and more often carried by children (up to 90%) this carriage may develop a natural immunity to the infection, but also is needed for invasive infection to develop. Evidence suggests that exposure of the hands to pathogens can lead to respiratory illnesses. We recently completed a pilot study which found that the hands were important vehicles for pneumococcal transmission. We further investigated if washing the hands with antibacterial soap would interrupt this transmission and protect against colonisation of bacteria in the nose. We will now test if washing the hands with antibacterial soap reduces spread of bacteria compared to washing with water

Who can participate?
We will recruit healthy adults who are at less risk of infection: healthy adults 18-50yrs old.

What does the study involve?
A few drops of live bacteria are put onto the hand of participants and we ask them to facilitate transmission into the nose by rubbing their noses and sniffing up. Participants will be randomly allocated to one of 3 groups:
Control: no intervention before transmitting bacteria
Intervention A: wash hands in water before transmitting bacteria
Intervention B: wash hands with antibacterial soap before transmitting bacteria

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in the study however we hope that participants will feel that they have contributed to a research project that could inform future handwashing practice and reduce the spread of infection.
The risks associated with the research relate to the sampling methods and the exposure to live bacteria. These are as follows:
-Nasal wash samples involve squirting some sterile saline inside the nose, this is then expelled and collected for processing. Some participants may swallow some of the saline however this is not uncomfortable.
-Blood sampling, we take a very small sample of blood at the beginning of the study (3ml). Some

participants may find this temporarily uncomfortable however the staff that perform this are trained and experienced in this process. On occasions, blood sampling can cause a small bruise of make the participant feel light headed. The volume taken during this study is highly unlikely however to make participants feel light headed.
-The risks associated with the exposure to live bacteria include pneumonia, meningitis or sepsis. We have however inoculated over 1400 healthy participants in 9 years and we have not experienced a single case of these diseases. We reduce the risk by providing the participant with 24/7 access to a member of the research team, a course of antibiotics to be taken in case of illness (under specific guidance of the research team), a safety information leaflet and a digital thermometer to check their temperature daily for the first 3-4 days and in the case of feeling unwell.

Where is the study run from?
The study will be conducted at the LSTM with clinical procedures being undertaken in the Accelerator Research Clinic (ARC) which is a LSTM sponsored research clinic on a NHS site.

When is the study starting and how long is it expected to run for?
April 2019 to April 2020

Who is funding the study?
Unilever, UK

Who is the main contact?
Dr. Helen Hill
2volresearch@lstmed.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Helen Hill

Contact details
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
2: 12/03/2019

Study information

Scientific Title
Lifebuoy Bar Soap Handwashing Randomised Controlled Trial

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)
Approved 10/04/2019, NHS HRA North West - Liverpool East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ; 0207104 8345; nrescommittee.northwest-liverpooleast@nhs.net); ref: 19/NW/0043

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
Nasal exposure with Streptococcus pneumoniae SPN6B. Randomised 1:1:1 to wash hands with water only: wash hands with Lifebuoy bar soap and water: no hand washing intervention before attempting to transmit SPN6B from hands to their nose.

Participants are randomised on the day of exposure by opening the randomisation envelope. The randomisation has been computer generated by a statistician from the tropical Clinical Trials Unit. The envelopes were then created by 2 staff that will not be involved in the daily running of the trial. The randomisation allocation will be recorded in the Case Report Form.

Intervention Type
Behavioural

Primary outcome(s)
Presence of SPN6 pneumococcal bacteria by classical microbiological culture at any time point post exposure (day 2, day 6/7 or day 9/10). The presence of pneumococcal bacteria will be

recorded as yes or no in the database and will be analysed according to the group allocation at the end of the study. We will also monitor density as a secondary outcome measure.

Key secondary outcome(s))
1. The occurrence of 6B pneumococcal colonisation determined by the presence of pneumococcus in NW at each time point post exposure (days 2, 6/7 and 9/10), detected using classical microbiology.
2. The density of 6B pneumococcal colonisation in NW at each time point following pneumococcal exposure (days 2, 6/7 and 9/10), detected using classical microbiology.
3. The area under the curve of 6B pneumococcal colonisation density following pneumococcal exposure (days 2, 6/7 and 9/10), detected using classical microbiology.
4. The duration of 6B pneumococcal colonisation determined by the last NW following pneumococcal exposure in which 6B pneumococcus is detected using classical microbiology
5. The occurrence of 6B pneumococcal colonisation determined by the presence of pneumococcus in NW 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.

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. 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
All

Total final enrolment

Key exclusion criteria
1. Previous pneumococcal vaccination
2. In a caring role or with intimate physical contact with at-risk individuals (children under 5yrs, immunosuppressed adults) during the period of pneumococcal colonisation
3. History of or current regular drug or alcohol abuse (frequently drinking alcohol: men and women should not regularly drink > 3-4 units/day and >2-3 units/day respectively)
4. Taking daily medications that may affect the immune system e.g. systemic steroids, systemic corticosteroids, antibiotics, or disease-modifying anti-rheumatoid drugs, roacutanne decision at the discretion of study doctors and PI
5. Any acute illness (new symptoms within preceding 14 days which are unexplained by the known past medical history)
6. Having received any antibiotics in the preceding 4 weeks
7. History of culture-proven pneumococcal disease requiring hospital admission
8. Involved in another clinical trial unless observational or in follow-up (non-interventional) phase.
9. Involved in a clinical trial involving EHPC and bacterial inoculation with SPN6B in the past three years (inoculation with other SPN strains may be included if >6months after inoculation)
10. Disease associated with altered immunity, including diabetes, alcohol abuse, malignancy, rheumatological conditions
11. At the clinician's discretion any unstable or poorly controlled co-morbidity
12. Taking medication that affects blood clotting (except aspirin and clopidogrel) e.g. warfarin or other oral or injectable anticoagulants
13. Have any uncontrolled medical/ surgical conditions such as but not restricted to: hypertension, mental health conditions, epilepsy, narcolepsy, chronic conditions requiring pain medication such as osteoarthritis, skin conditions, allergies, hay fever, and any other condition at the discretion of the PI.
14. Allergy to penicillin/amoxicillin AND clarithromycin (or other macrolides)
15. Concern of the study doctor about the participant's health
16. 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
17. Pregnancy - minimise risk of pneumococcal disease
18. History of Smoking
18.1 Current or ex-smoker (regular cigarettes: smokes daily/ smokes >5 cigarettes per week, e-cigarette/vaping and recreational drugs) in the last 6 months
18.2 Recent smoker i.e. within the last 6 months - minimise risk of pneumococcal disease
18.3 Ex-smoker with a significant smoking history (>10 pack years) – minimise risk of pneumococcal disease

Date of first enrolment
15/04/2019

Date of final enrolment
28/11/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Accelerator Research Clinic, Liverpool School of Tropical Medicine
Accelerator Research Clinic, 3rd Floor
Liverpool Life Sciences Accelerator Building
1 Daulby Street
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Sponsor information

Organisation
Liverpool School of Tropical Medicine

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

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet		08/04/2019	23/05/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes