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Nose and throat study

Submission date 03/07/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/07/2017	**Overall study status** Completed	
Last Edited 05/09/2023	**Condition category** Ear, Nose and Throat	

Plain English Summary

Background and study aims
Pneumococcus is a bacteria that can be found in the nose and throat. Usually, those who carry the bacteria do not know it. Pneumococcus can cause serious infections such as pneumonia (infection of the lungs), sepsis and meningitis, especially in those who are more vulnerable such as young children and older adults. Usually this bacteria is present in the nose of health adults and does not cause any illness. Having a small amount of it in the nose may protect people against disease. In order to make a new vaccine against pneumonia, it is important to understand how it protects against disease. The established Experimental Pneumococcal Carriage Model (EHPC) allows healthy volunteers to carry these bacteria in their nose safely and to then take biopsies (tissue samples) to see what the response is to the bacteria. This study aims to find out the type of immune responses that evolve in the nose and throat during nasal carriage of pneumococcus bacteria.

Who can participate?
Adults aged 18 to 50 years old speak fluent English.

What does the study involve?
Participants are allocated to one of two groups based on if they are healthy participants or if they are NHS patietns. Those in the first group are given a few drops of the bacteria in the nose followed by careful monitoring. They are then given a three day course of antibiotics. Participants undergo a nasal or tonsil biopsy (where a sample of the nose or tonsils is taken) at either ten or 23 days after the bacteria is placed in their nose. Those in the second group also receive the same programme and have their nasal or tonsil biopsy taken at 23 days after the bacteria is placed in their nose.

What are the possible benefits and risks of participating?
There are no notable benefits with participating; however participants are paid for their time. There are potential risks with the study such as unexpected abnormalities.

Where is the study run from?
1. Royal Liverpool University Hospital (UK)
2. University Hospital Aintree (UK)

When is the study starting and how long is it expected to run for?
August 2016 to September 2018

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Ms Lepa Lazarova
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Study website
www.lstmed.ac.uk/pneumoniavaccine

Contact information

Type(s)
Public

Contact name
Ms Lepa Lazarova

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33516

Study information

Scientific Title
Early and late nasal and tonsil cell responses during human pneumococcal colonisation

Study hypothesis

This study aims to find out the type of immune responses that evolve in the nose and throat during nasal carriage of pneumococcus bacteria.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West- Liverpool East Research Ethics Committee, 01/02/2017, ref: 17/NW/0029

Study design
Non-randomised; Both; Design type: Process of Care, Surgery, Cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Condition
Specialty: Ear, nose and throat, Primary sub-specialty: Ear, nose and throat; UKCRC code/ Disease: Inflammatory and Immune System/ Certain disorders involving the immune mechanism

Interventions
This study consists of two phases:

Phase One (optimisation group):
Participants who are undergoing planned (elective) operations will be asked permission for a biopsy to be taken from the nose and the tonsil during the operation.

Phase Two:
Participants are allocated to one of two groups based on if they are healthy participants or the NHS patients. All participants undergo the following steps:

Group One Healthy participants: Participants receive a few drops of the pneumococcus bacteria in the nose at baseline. They then are given a three-day course of Amoxicillin 500 mg antibiotics prior to the day of biopsy. Participants have a nasal biopsy either on day ten or day 23 after the inoculation depending on the carriage status. The day of the biopsy is the last day of the study participation.

Group Two NHS patients: Participants receive a few drops of the pneumococcus bacteria in the nose at baseline.They are then given a three-day course of Amoxicillin 500 mg antibiotics prior to the day of biopsy. Participants in this group receive a nasal and tonsillar biopsy at 23 days post inoculation. The day of the biopsy is the last day of the study participation.

Intervention Type
Other

Primary outcome measure
Percentage of cell populations are measured using the nasal/tonsil biopsy at day 10 and 23 post inoculation.

Secondary outcome measures
Percentage of cell populations are measured between carriage positive and carriage negative subjects at day 10 and day 23. Association between early induction of specific genes with percentages of cell populations are measured in carriage -positive subjects.

Overall study start date
01/08/2016

Overall study end date
02/09/2018

Eligibility

Participant inclusion criteria
Phase 1:
1. Have capacity to give informed consent
2. Aged 18-50 years (ages chosen to minimise discrepancy in the immune response and to minimise the risk of pneumococcal disease)
3. Speak fluent English (to ensure a comprehensive understanding of the research project and their proposed involvement, in order to minimise any communication issues to maximize participant safety)

Phase 2:
1. Have capacity to give informed consent
2. Aged 18-50 years (ages chosen to minimise discrepancy in the immune response and to minimise the risk of pneumococcal disease)
3. Speak fluent English (to ensure a comprehensive understanding of the research project and their proposed involvement, in order to minimise any communication issues to maximize participant safety)
4. Consented for elective nasal septum and or turbinate surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
Planned Sample Size: 45; UK Sample Size: 45

Total final enrolment
20

Participant exclusion criteria
Stage One-Optimization group
1. Chronic rhinosinusitis (CRS) with or without nasal polypoidal disease
2. Use of oral of nasal steroid spray up to the day of surgery
3. Currently involved in another study unless observational or in follow-up phase (non-interventional)

Stage Two
Group One
1. Currently involved in another study unless observational or in follow-up phase (non-interventional)
2. Close contact with at risk individuals (children under 5 years, immunosuppressed adults, elderly, chronic ill health) – to minimise risk of pneumococcal transmission
3. Current regular smoker (smokes daily) or previous regular smoker that has stopped smoking less than 12 months ago (< 10 years).
4. Asthma or respiratory disease – to minimise risk of pneumococcal disease
5. Current acute or chronic rhinosinusitis with or without nasal polypoidal disease
6. Pregnant - to minimise the risk of pneumococcal disease
7. Allergic to penicillin or amoxicillin
8. Allergic to local anaesthetic
9. On medication that may affect the immune system in any way e.g. steroids
10. Been involved in a clinical trial involving EHPC over the last 3 years
11. Current acute severe febrile illness
12. Taking long term antibiotics
13. On oral anti-platelets or warfarin therapy

Group Two
1. Currently involved in another study unless observational or in follow-up phase (non-interventional)
2. Close contact with at risk individuals (children under 5 years, immunosuppressed adults, elderly, chronic ill health) – to minimise risk of pneumococcal transmission
3. Current regular smoker (smokes daily) or previous regular smoker that has stopped smoking less than 12 months ago (< 10 years).
4. Asthma or respiratory disease – to minimise risk of pneumococcal disease
5. Current acute or chronic rhinosinusitis with or without nasal polypoidal disease
6. Pregnant - to minimise the risk of pneumococcal disease
7. Allergic to penicillin or amoxicillin

8. On medication that may affect the immune system in any way e.g. steroids,
9. Been involved in a clinical trial involving EHPC over the last 3 years
10. Current acute severe febrile illness
11. Taking long term antibiotics
12. Previous tonsillectomy

*Participants that have been started on nasal steroid spray to relive the nasal blockage symptoms will be advised to stop **Participants in Group 2 on oral anti-platelets therapy of warfarin are advised to stop the medication up to seven days prior to their elective nasal surgery and additional nasal and tonsillar biopsy to minimise the risk of bleeding as per the pre-operative assessment clinic advise.

Recruitment start date
02/05/2017

Recruitment end date
02/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
University Hospital Aintree
Longmoor Lane
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation
Liverpool School of Tropical Medicine

Sponsor details
Research and Development
Pembroke Place
Liverpool
England
United Kingdom
L3 5QA

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings from this study will be disseminated amongst the scientific community. We intend to publish our findings in peer reviewed scientific journals and present data at appropriate local, national and international conferences. In addition, we will produce a lay report of our findings which will be made available to all participants.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

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
Results article		30/07/2019	05/09/2023	Yes	No