

# Nose and throat study

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| <b>Submission date</b><br>03/07/2017   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>11/07/2017 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>05/09/2023       | <b>Condition category</b><br>Ear, Nose and Throat | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### 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 patients. 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  
Lepa.Lazarove@lstmed.ac.uk

**Study website**  
[www.lstmed.ac.uk/pneumoniavaccine](http://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 objectives**

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

### **Health condition(s) or problem(s) studied**

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

## **Completion date**

02/09/2018

# **Eligibility**

## **Key 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

**Key exclusion criteria**

Stage One-Optimization group

1. Chronic rhinosinusitis (CRS) with or without nasal polypoidal disease
2. Use of oral or 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 relieve 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.

**Date of first enrolment**

02/05/2017

**Date of final enrolment**

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)**

Medical Research Council (United Kingdom), 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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |
| <a href="#">Results article</a>      |         | 30/07/2019   | 05/09/2023 | Yes            | No              |