

# Understanding meningococcal carriage and disease in healthy teenagers

<b>Submission date</b> 17/09/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/12/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/08/2020	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Meningococci are a type of bacteria that cause serious infections. They are usually carried harmlessly in the oropharynx (part of the throat) but sometimes cause devastating disease. The trialists collected samples of meningococci carried by 14,000 – 18,000 sixth form students for three consecutive years between 1999 and 2001, before and after the introduction of meningococcal C conjugate (MCC) vaccines. This corresponded to a time of unprecedented meningococcal disease incidence, the highest seen in the postwar period and 45 times higher than current disease incidence. The trialists propose to collect a similar sample of carried meningococci 15 years later at a time of unusually low disease incidence and prior to any changes in the national immunization schedule involving MCC vaccine boosters to teenagers and the introduction of the novel vaccine Bexsero® into the infant schedule. We will then carry out a genetic study comparing disease and carriage meningococci from high and low incidence periods. This study aims to answer the following questions: What are the genetic characteristics that define invasive epidemic meningococci? How has the population of meningococci changed over the last 15 years? What are the risk factors for meningococcal carriage?

### Who can participate?

Participants should be in school years 12 or 13 (S5 and S6 in Scotland) and aged 15-19 years in full-time or part-time education, or aged 16-19 years in the general community.

### What does the study involve?

It involves taking a single swab from the back of the throat and completing a brief questionnaire about participants and their lifestyle. In Glasgow, a single saliva sample is also collected.

### What are the possible benefits and risks of participating?

By taking part, participants help improve understanding of meningococcal disease and carriage, and how to use vaccines to best protect other people in the future. There is no direct benefit to participants themselves. Some people find a throat swab either tickly or a bit unpleasant but this only lasts only a few seconds.

### Where is the study run from?

University of Oxford (UK)

When is the study starting and how long is it expected to run for?  
September 2014 to August 2015

Who is funding the study?  
Wellcome Trust (UK)

Who is the main contact?  
Dr Jenny MacLennan

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Jenny MacLennan

**Contact details**  
Department of Zoology  
University of Oxford  
South Parks Road  
Oxford  
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OX1 3PS

## Additional identifiers

**Protocol serial number**  
17214

## Study information

**Scientific Title**  
A multicentre cross-sectional study of meningococcal oropharyngeal carriage in healthy teenagers in the UK

**Study objectives**  
Background: Meningococci are usually carried harmlessly in the oropharynx but sometimes cause devastating invasive disease. The trialists undertook surveys of oropharyngeal carriage of meningococci for three consecutive years between 1999 and 2001 before and after the introduction of meningococcal C conjugate (MCC) vaccines and established large collections of carried isolates. This corresponded to a time of unprecedented meningococcal disease incidence, the highest seen in the postwar period and 45 times higher than current disease incidence. The trialists propose to collect a similar sample of carried meningococci 15 years later at a time of unusually low disease incidence and prior to any changes in the national immunization schedule involving MCC vaccine boosters to teenagers and the introduction of the novel vaccine Bexsero® into the infant schedule. These samples will form the basis of a genetic association study of the whole genome sequences of representative disease and carriage meningococcal isolates from high and low incidence periods.

Questions it will answer: What are the genetic characteristics that define invasive epidemic meningococci? How has the population of meningococci changed over the last 15 years? What are the risk factors for meningococcal carriage?

Why is this important?: By comprehensively cataloguing genome-wide meningococcal variation in well characterized isolates with different phenotypes, these studies will identify the population of circulating meningococci, and will improve our understanding of epidemic meningococci and why meningococcal disease incidence varies over time.

Potential benefits: This research will help guide decisions on national immunisation strategies for meningococcal vaccines in the future.

Study design: A multicentre cross-sectional observational survey of meningococcal carriage with a questionnaire in 18,000 healthy teenagers aged 15-19 years.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

First MREC approval date 18/08/2014, ref: 14/SC/1163

### **Study design**

Non-randomised; Observational; Design type: Cross-sectional study

### **Primary study design**

Observational

### **Study type(s)**

Screening

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

Topic: Children, Primary Care; Subtopic: All Diagnoses, Other Primary Care; Disease: All Diseases, All Diseases

### **Interventions**

Estimating the rate of oropharyngeal carriage of *Neisseria meningitidis* and the risk factors for carriage in sixth form students at a single visit with no follow up.

### **Intervention Type**

Other

### **Primary outcome(s)**

Rates of oropharyngeal carriage of *Neisseria meningitidis* measured at baseline as determined by culture of *Neisseria meningitidis* from a throat swab

### **Key secondary outcome(s)**

1. To determine rates of meningococcal carriage according to the serogroup and genogroup of cultured organisms from the throat swab
2. To identify risk factors associated with meningococcal carriage as determined by answers to a

one-page questionnaire

3. To evaluate the relationship between salivary antibodies, smoking and meningococcal carriage as determined by measurements from saliva samples from Glasgow students

**Completion date**

31/08/2015

## **Eligibility**

**Key inclusion criteria**

1. Participant is willing and able to give informed consent for participation in the study
2. Male or female
3. In school years 12 or 13 (S5 and S6 in Scotland) and aged 15-19 years in full time or part time education, or aged 16-19 years in the general community

Target Gender: Male & Female; Upper Age Limit 19 no age limit or unit specified; Lower Age Limit 15 no age limit or unit specified

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

15 years

**Upper age limit**

19 years

**Sex**

All

**Key exclusion criteria**

1. Not willing or able to give informed consent
2. Outside the specified age range

**Date of first enrolment**

01/09/2014

**Date of final enrolment**

31/08/2015

## **Locations**

**Countries of recruitment**

United Kingdom

**Study participating centre**  
**University of Oxford**  
Oxford  
United Kingdom  
OX1 3PS

## **Sponsor information**

**Organisation**  
University of Oxford (UK)

**ROR**  
<https://ror.org/052gg0110>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
Wellcome Trust (UK)

**Alternative Name(s)**

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
International organizations

**Location**  
United Kingdom

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes