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Understanding meningococcal carriage and disease in healthy teenagers

Submission date
17/09/2014

Recruitment status
No longer recruiting

Registration date
10/12/2014

Overall study status
Completed

Last Edited
12/08/2020

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
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

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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

Primary study design
Observational

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

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?
HRA research summary			26/07/2023	No	No
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