

The Bristol Meningococcal Natural History of Carriage study

Submission date 04/02/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/04/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/02/2022	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The meningococcus is a bug that commonly lives at the back of the throat without causing any symptoms in people carrying it. Meningitis and blood poisoning are very serious diseases that can be caused by meningococcus (and some other bugs). Although only very few people get these diseases, teenagers and young children are at increased risk. A national meningococcal carriage study in seven UK sites is collecting one throat swab each from 18,000 healthy 15-19 year old school/college students. Of these, around 2,500 will be recruited in Bristol. The national study will show how many teenagers were carrying the bug on the day they had their swab taken, but it cannot show whether or how this changes over time. This new study is a follow-on to the national study. The aim of this additional study is to look at the natural changes in meningococcus carriage in greater detail.

Who can participate?

Healthy male and female students aged 15 to 19 years attending participating schools/colleges in Bristol who are enrolled in the meningococcal carriage study, and who agreed to be re-approached for this study.

What does the study involve?

Five further (monthly) throat swabs are taken from 1,000 of the Bristol participants of the national study. The participants are also asked to complete a brief questionnaire about factors that may affect meningococcus carriage (smoking, antibiotic use etc) at the time of each swab. The aims are to find out whether some people carry a larger number of bugs than others (high versus low carriers), whether the amount of bug carried changes over time, how many people naturally stop carrying the bug, and how many who didn't previously have it start carrying it (acquisition).

What are the possible benefits and risks of participating?

Understanding exactly how meningococcus carriage varies naturally provides important information to help use existing vaccines more effectively and develop better ones in the future.

Where is the study run from?

University of Bristol (UK)

When is the study starting and how long is it expected to run for?
November 2014 to June 2017

Who is funding the study?
National Institute of Health Research (NIHR) Health Protection Research Unit (HPRU) Evaluation of Interventions (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
17811

Study information

Scientific Title

Follow on study of meningococcal carriage in 15-19 year old school students: description of the natural history of colonisation and development of laboratory and epidemiological tools for detailed studies of the potential impact of novel vaccines upon transmission

Study objectives

Aim: To provide a detailed picture of the natural history of meningococcal carriage in adolescents in whom carriage and transmission is relatively common, and who are a potential target group both for vaccine studies to evaluate impact on carriage and transmission, and ultimately for intervention with universal immunisation programmes.

Objectives: Among 15-19 year old students in Bristol, UK:

1. Describe the distribution of carriage density
2. Provide detailed information on the duration of carriage
3. Provide detailed information on rates of acquisition of carriage
4. Clarify heterogeneity in patterns of carriage and specifically to what extent high density and long duration carriage characterises one or more specific subgroups of individuals

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London - Bromley, 14/07/2014, ref: 14/LO/1332

Study design

Non-randomised; Observational; Design type: Cohort study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Children; Subtopic: All Diagnoses; Disease: All Diseases

Interventions

Oropharyngeal swab, 5 swabs, one at each visit; questionnaire, 5 short questionnaires on risk factors of meningococcal carriage, one at each visit; Study Entry: Registration only

Intervention Type

Other

Primary outcome(s)

Distribution of carriage density; Timepoint(s): At entry and over the course of the study

Key secondary outcome(s)

1. Acquisition of carriage; Timepoint(s): rates over the course of the study
2. Duration of carriage; Timepoint(s): Over the course of the study
3. Patterns of carriage; Timepoint(s): heterogeneity over study period between subgroups, especially high density and long duration carriage

Completion date

30/06/2017

Eligibility

Key inclusion criteria

The study will recruit healthy male and female students aged 15 to 19 years attending participating schools/colleges in Bristol who are enrolled in the Wellcome Trust funded cross-sectional meningococcal carriage study, and whose consent for that study included agreement to potentially be re-approached concerning this study. All subjects must provide signed informed consent to participate in this longitudinal study.

Target Gender: Male & Female; Upper Age Limit 19 years ; Lower Age Limit 15 years

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Child

Lower age limit

15 years

Upper age limit

19 years

Sex

All

Key exclusion criteria

Any medical condition or circumstances which, in the opinion of the investigator, will jeopardise the likelihood of safe or effective participation in the study

Date of first enrolment

05/11/2014

Date of final enrolment

31/03/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**Bristol Children's Vaccine Centre**

Level 6, Education & Research Centre

Upper Maudlin Street

Bristol

United Kingdom

BS2 8AE

Sponsor information

Organisation

University of Bristol

ROR

<https://ror.org/0524sp257>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2021	18/02/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes