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The Bristol Meningococcal Natural History of Carriage study

Submission date	Recruitment status	[_] Prospectively registered
04/02/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/04/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/02/2022	Other	

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

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Other

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

Secondary outcome measures
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

Overall study start date
05/11/2014

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

Age group
Child

Lower age limit
15 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
Planned Sample Size: 1000; UK Sample Size: 1000

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
England

United Kingdom

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

Sponsor details
Senate House
Tyndall Avenue
Bristol
England
United Kingdom
BS8 1TH

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
30/06/2018

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