ISRCTN75858406 https://doi.org/10.1186/ISRCTN75858406

Be on the TEAM: Teenagers Against Meningitis

Submission date
12/03/2018

Registration date
14/03/2018

Last Edited
20/03/2026

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Teenagers and young children are at increased risk of diseases such as meningitis and blood poisoning due to bacteria called meningococcus. Although these diseases can be serious, the meningococcus bacteria are carried in the back of the throat of 1 in 10 teenagers without causing any symptoms. Most meningococcal disease in teenagers is due to Meningitis B (also known as MenB). The aim of this study is to see whether immunising teenagers with vaccines against MenB can reduce the number of teenagers carrying these bacteria in their throat. This would be important because it could mean that teenage MenB immunisation would not only help protect teenagers against these potentially deadly diseases, but also that babies, children and older adults are less likely to be exposed to the bacteria. In short, immunising teenagers with a MenB vaccine might mean lower rates of meningococcal disease across all ages.

Who can participate?
Students aged 16-18 attending year 12 (or equivalent) at one of the participating 6th form colleges in England, Scotland and Wales

What does the study involve?
Participating schools are randomly allocated to deliver one of two types of MenB vaccine: 4CMenB (also known as Bexsero) and MenB-fHBP (also known as Trumenba). Participants either get two doses of 4CMenB or MenB-fHBP given 6 months apart at their first two study visits, or two doses of 4CMenB 1 to 6 months apart at their last two study visits. These vaccines are approved for use in the UK, but are not routinely given to teenagers in this country. Samples are collected from the participants' throats to compare rates of MenB carriage before and after getting the MenB vaccine. Teenagers have three study visits over 12 to 18 months and all visits take place within schools.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Oxford(UK)

When is the study starting and how long is it expected to run for?
October 2017 to April 2024

Who is funding the study?
1. Department of Health (UK)
2. Pfizer (UK)

Who is the main contact?
Emma Plested, info@ovg.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Emma Plested

Contact details
Oxford Vaccine Group, University of Oxford
CCVTM
Churchill Hospital
Headington
Oxford
United Kingdom
OX3 7LE

Additional identifiers

Clinical Trials Information System (CTIS)
2017-004609-42

Central Portfolio Management System (CPMS)
37350

Study information

Scientific Title
Evaluating the effect of immunisation with group B meningococcal vaccines on meningococcal carriage

Acronym
BOTT

Study objectives
Teenagers and young children are at increased risk of diseases such as meningitis and blood poisoning due to bacteria called meningococcus. Although these diseases can be serious, the meningococcus bacteria are ‘carried’ in the back of the throat of 1 in 10 teenagers without causing any symptoms. Most meningococcal disease in teenagers is due to Meningitis B (also known as MenB). The aim of this study is to find out whether immunising teenagers with vaccines against MenB can reduce the number of teenagers carrying these bacteria in their throat. This would be important because it could mean that teenage MenB immunisation would

not only help protect teenagers against these potentially deadly diseases, but also that babies, children and older adults are less likely to be exposed to the bacteria. In short, immunising teenagers with a MenB vaccine might mean lower rates of meningococcal disease across all ages.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central – Berkshire B Research Ethics Committee, 02/03/2018, ref: 18/SC/0055

Primary study design
Interventional

Study design
Non-randomised; Both; Design type: Prevention, Vaccine, Cross-sectional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Vaccination against meningitis

Interventions
Vaccines are randomly allocated by the project statistician on a site by site basis. Sites remain assigned to one vaccine group only for the duration of the study. Two types of MenB vaccine are used: 4CMenB (also known as Bexsero) and MenB-fHBP (also known as Trumenba). Participants in this study will either get two doses of 4CMenB or MenB-fHBP given 6 months apart at their first two study visits, or two doses of 4CMenB 1 to 6 months apart at their last two study visits. These vaccines are approved for use in the UK, but are not routinely given to teenagers in this country. The two doses of MenB vaccine will be given by IM injection into the deltoid by trained research nurses/doctors within the school setting. Oropharyngeal samples are collected from teenager's throats to compare rates of MenB 'carriage' in teenagers before and after getting a MenB vaccine. Teenagers have three study visits, over 12 to 18 months and all visits would be held within schools. The follow up is 13 months for group 1 + 2 and up to 18 months for group 3.

Intervention Type
Biological/Vaccine

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Bexsero, Trumenba

Primary outcome(s)
Rates of carriage prevalence of any of meningococci genogroup B, C, W , X and Y before and after immunisation in both immunisation cohorts, compared with unimmunised controls; Timepoint(s): End of the study

Key secondary outcome(s)

Rates of carriage prevalence of particular Neisseria before and after immunisation in both immunisation cohorts, compared with controls, specifically:
1. Serogroup B meningococci
2. Hyper-invasive meningococcal strains
3. All meningococcal strains
4. Other Neisseria species
5. Meningococci of other non B serogroups and capsule null meningococci
6. Meningococci expressing antigens contained in 4CMenB and MenB-fHBP
The difference in acquisition of carriage of all N. meningitidis over a 12-month period in both immunised cohorts compared to unvaccinated participants

Completion date
10/04/2024

Eligibility

Key inclusion criteria
1. Male or female, aged 16-18 years attending year 12 (or equivalent) at one of the participating 6th form colleges in England, Scotland and Wales
2. Participant is willing and able to give informed consent for participation
3. In the Investigator's opinion, is able and willing to comply with all trial requirements.
4. Willing to have bacterial isolates from throat swabs stored for future research in ethically approved studies
5. Willing to allow his or her General Practitioner to be contacted to confirm vaccination status if necessary

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
18 Years

Sex
All

Total final enrolment
24047

Key exclusion criteria

1. Evidence of a course of either 4CMenB or MenB-fHBP in the past (documentation or self-report)
2. History of anaphylaxis to any component of 4CMenB or MenB-fHBP
3. Any other significant disease or disorder which, in the opinion of the investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participants ability to participate
4. Participant is known to be pregnant

Date of first enrolment
19/03/2018

Date of final enrolment
22/12/2019

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Royal Alexandra Children's Hospital
BSUHT
Eastern Road
East Sussex
Brighton
England
BN2 5BE

Study participating centre
Bristol Children's Vaccine Centre
Level 6
Education and Research Centre
Upper Maudlin Street
Bristol
England
BS2 8AE

Study participating centre

Public Health Wales
4th Floor, Number 2 Capital Quarter
Tyndall Street
Cardiff
Wales
CF10 4BZ

Study participating centre
Health Protection Scotland
4th Floor, Meridian Court
5 Cadogan Street
Glasgow
Scotland
G2 6QE

Study participating centre
St Mary's Hospital
Praed St
London
England
W2 1NY

Study participating centre
Research and Development Department
Above Breast Care Centre – First floor
Maidstone Hospital
Hermitage Lane
Maidstone
England
ME16 9QQ

Study participating centre
Paediatric Research Team
5th Floor
Royal Manchester Children's Hospital
Oxford Road
Manchester
England
M13 9WL

Study participating centre

University of Nottingham Health Service
University Park
Derby Rd
Nottingham
England
NG7 2QW

Study participating centre
Oxford Vaccine Group
CCVTM
Churchill Hospital
Oxford
England
OX3 7LE

Study participating centre
Research & Development
The Lantern centre
Vicarage Lane
Fulwood
Preston
England
PR2 8DW

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
St George's, University of London
Cranmer Terrace
London
England
SW17 0RE

Study participating centre

Research and Innovation
Room F08, Pinewood House
Stockport NHS Foundation Trust
Stepping Hill Hospital
Stockport
England
SK2 7JE

Study participating centre
Clinical Trials Unit
Wrightington Hospital
Hall Lane
Appley Bridge
England
WN6 9EP

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Department of Health; Grant Codes: PR-R18-0117-21001

Funder Name
Pfizer UK

Alternative Name(s)
Pfizer Ltd, Pfizer Limited

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/10/2020	26/10/2020	Yes	No
Basic results		20/03/2026	20/03/2026	No	No
HRA research summary			28/06/2023	No	No
Other publications	Observational study of the vacccination programme	13/07/2022	18/06/2025	Yes	No
Protocol file	version 7.0	28/02/2022	09/05/2022	No	No
Protocol file	version 8.1	15/12/2023	08/01/2024	No	No