

Multiboost - MCC plus pertussis booster in adolescents

Submission date 22/07/2013	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 22/07/2013	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 21/06/2019	Condition category Infections and Infestations	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2012-005273-31

Protocol serial number
14867

Study information

Scientific Title

A phase III/IV randomised open-label study and comparison of the immunogenicity and safety of a single adolescent booster dose of a meningococcal group C conjugate-containing booster vaccine (Meningitec™, or Menjugate™, or NeisVac-C™, or Menitorix™), when given concurrently with an acellular pertussis-containing booster vaccine (Repevax™ or IPV-Boostrix™)

Study objectives

The aim of this study is to assess how well adolescent booster dose of a meningococcal group C conjugate-containing booster vaccine is tolerated when given concurrently with an acellular pertussis-containing booster vaccine in adolescents aged between 14-17 years.

Ethics approval required

Old ethics approval format

Ethics approval(s)

13/LO/0681

Primary study design

Interventional

Study design

Randomised interventional trial; Design type: Prevention, Treatment

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Topic: Medicines for Children Research Network, Primary Care Research Network for England;
Subtopic: All Diagnoses, Not Assigned; Disease: All Diseases

Interventions

Boostrix-IPV, Combination dTaP3/IPV vaccine
Meningitec, Meningococcal serogroup C conjugate vaccine
Menitorix, Combined meningococcal serogroup C and Hib conjugate vaccine
Menjugate, Meningococcal serogroup C conjugate vaccine
NeisVac-C, Meningococcal serogroup C conjugate vaccine
Repevax, Combined dTaP5/IPV vaccine

Follow Up Length: 1 month

Study Entry : Single Randomisation only

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Meningitec, Menitorix, Menjugate, NeisVac-C, Repevax, Boostrix-IPV

Primary outcome(s)

Meningococcal serogroup C-specific and pertussis-specific immune response

Key secondary outcome(s)

1. Safety and tolerability of each study combination of MCC and pertussis-containing vaccine
2. Tetanus, diphtheria, and (in appropriate study arms) Hib immune response

Completion date

12/03/2015

Eligibility**Key inclusion criteria**

1. Participant is willing and able to give written informed consent for participation. If aged below 16 years, parent/legal guardian gives consent while the participant gives written assent for participation in the study.
2. Male or female aged 14 years (+0 day) to 17 years (+364 days) on the day of consent.
3. Completed MCC and pertussis vaccination according to the UK (catch-up and/or routine) schedule appropriate for the participants age

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

388

Key exclusion criteria**Exclusion Criteria**

The participant may not enter the study if ANY of the following apply:

1. Any contraindication to vaccination as specified in the Green Book- Immunisation against Infectious Disease, HMSO.
2. Significant illness including progressive neurological disease or seizure disorder; confirmed or suspected immunosuppressive or immunodeficient conditions; major congenital defects; or known bleeding diathesis (or any condition that may be associated with a prolonged bleeding time).
3. Any other significant condition or circumstance which, in the opinion of the investigator, may either put the participant at risk because of participation in the study, or may influence the result of the study, or the participants ability to participate in the study.
4. History of invasive meningococcal disease or pertussis.
5. Significant contact (household or intimate exposure) to an individual with culture proven *Neisseria meningitis* disease or pertussis in the previous 60 days.

6. Any MCC or pertussis vaccination that is not according to the UK (catch-up or routine) schedule appropriate for the participants age.

7. Pregnancy

Temporary Exclusion Criteria

1. Fever (sublingual temperature $\geq 38^{\circ}\text{C}$)
2. Received systemic antibiotic(s) (either oral or parenteral) within the past 7 days. For all visits, if allowed by the study visit window, receipt of systemic antibiotics (either oral or parenteral) will delay venepuncture until at least 7 days after cessation of antibiotics.
3. Received any blood or blood products within the past 12 weeks.
4. Received another investigational agent within 90 days - or before completion of the safety follow-up period in another study, whichever is longer, prior to enrollment and unwilling to refuse participation in another investigational trial to the end of this study.
5. Possibility of pregnancy: All female potential participants will be assessed for the possibility of being pregnant. Assessment will be in accordance with SOP CTSOP071 (Pregnancy Testing and Exclusion from Studies). If there is a possibility of being pregnant, they will be advised to consult their own GP for a pregnancy test. They can only be considered for recruitment if they choose to take a test and are negative.

Date of first enrolment

12/08/2013

Date of final enrolment

12/03/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Centre for Infections

London

United Kingdom

NW9 5EQ

Sponsor information

Organisation

Health Protection Agency (HPA)

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

Department of Health - Policy Research Programme

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?
Basic results	Study website	11/11/2025	21/06/2019	No	No
HRA research summary			28/06/2023	No	No
Study website			11/11/2025	No	Yes