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Multiboost - MCC plus pertussis booster in adolescents

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/ClinicalTrials/NVECCurrentStudies/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2012-005273-31

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised interventional trial; Design type: Prevention, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet

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
Boostriv-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, Boostriv-IPV

Primary outcome measure
Meningococcal serogroup C-specific and pertussis-specific immune response

Secondary outcome measures
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

Overall study start date
12/08/2013

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

Age group
Adult

Sex
Both

Target number of participants

Planned Sample Size: 880; UK Sample Size: 880; Description: 110 participants per group, over 8 groups = 880 total. To account for attrition we will use a +/10% tolerance around these figures

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 >= 38°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
England

United Kingdom

Study participating centre
Centre for Infections
London
United Kingdom
NW9 5EQ

Sponsor information

Organisation
Health Protection Agency (HPA)

Sponsor details
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61 Colindale Avenue
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NW9 5EQ

Sponsor type
Government

Website
http://www.hpa.org.uk/

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Department of Health - Policy Research Programme

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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			21/06/2019	No	No
HRA research summary			28/06/2023	No	No