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Men B vaccination in preterm infants: a comparison of two schedules

Submission date
31/07/2017

Recruitment status
No longer recruiting

Registration date
10/07/2019

Overall study status
Completed

Last Edited
20/04/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Meningitis (infection of the lining of the brain) and septicaemia (blood poisoning) have many causes; an important cause in the UK is a bacteria called Meningococcus. Vaccination protects against some forms of Meningococcus by encouraging the body to make antibody to the bacteria - a chemical which helps fight the bacteria if it is encountered. In the UK babies are vaccinated according to the same schedule whether they are born early (preterm) or on time, but there are concerns that preterm babies may not respond as strongly to their vaccinations - this may result in less protection. In 2015 a new vaccine, the Men B vaccine, was introduced. There have been no studies done to determine whether this will work as well in preterm babies compared with term babies. This study will compare responses made by babies who are vaccinated according to two different schedules. This could help doctors make decisions about what programme should be followed for preterm babies.

Who can participate?
Premature babies born before 35 weeks of pregnancy

What does the study involve?
Parents are approached about the study and provided with information. If parents wish their baby to take part in the study they are asked to sign a consent form. Babies are randomly allocated to receive their Men B vaccine (Bexsero) according to one of two schedules - they either receive two doses of Men B vaccine at 2 and 4 months or three doses of Men B vaccine at 2, 3 and 4 months alongside their routine vaccinations given according to the UK schedule. Parents are asked to complete a diary card for one week following each set of vaccinations. Blood sampling is performed at 5, 12 and 13 months. These blood samples are to measure the amount of antibody (a protein which fights infection) following Men B vaccination to compare the two schedules to see if one gives better protection to babies born preterm.

What are the possible benefits and risks of participating?
If, after the booster vaccination, the baby is found to have a low response to vaccination they are offered an additional booster vaccine. This study involves the administration of vaccines which are given as part of the routine vaccination schedule. Whilst all vaccinations carry a very small risk of adverse reactions this is not greater for those taking part in the study compared

with those receiving the vaccinations as part of routine care and all vaccines given as part of the study are given by members of staff trained in vaccine administration and the management of adverse reactions. The study involves blood samples being obtained which can be associated with discomfort and bruising, but these samples will be collected by staff who are trained in obtaining blood samples from babies and local anaesthetic cream can be used for the blood sampling.

Where is the study run from?
1. St George's Hospital (UK)
2. John Radcliffe Hospital (UK)
3. Churchill Hospital (UK)
4. Norfolk and Norwich University Hospital (UK)
5. Queen Alexandra Hospital (UK)
6. Southampton General Hospital (UK)
7. Royal Cornwall Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2016 to March 2020

Who is funding the study?
1. GlaxoSmithKline
2. Meningitis Now

Who is the main contact?
1. Dr Anna Calvert
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2. Jennifer Stuart
jstuart@sgul.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
2017-001487-38

Protocol serial number
CPMS: 34643

Study information

Scientific Title
Babies born Early Antibody Response to Men B vaccination: BEAR Men B

Acronym
BEAR Men B

Study objectives
To investigate the antibody response in preterm infants to two different schedules of Men B vaccine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/05/2017, Yorkshire & The Humber- Sheffield Research Ethics Committee (Room 001, Jarrow Business Centre, Rolling Mill Road, Jarrow, Tyne and Wear, NE32 3DT, UK; Tel: +44 (0)207 1048082; Email: nrescommittee.yorkandhumber-sheffield@nhs.net), ref: 17/YH/0150

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Prevention, Vaccine

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Meningitis

Interventions
Babies will be randomised in a 1:1 ratio to receive two doses (at 2 and 4 months) or three doses (at 2, 3 and 4 months) of Men B vaccine (Bexsero) in their primary vaccination series. All babies will receive their other routine vaccinations according to the UK schedule which will include a booster dose of Men B vaccine (Bexsero) at the age of 12 months.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Primary outcome(s)
Antibody response to Men B vaccination assessed using serum bactericidal antibody (SBA) assays performed on samples collected at 5 months (post primary), 12 months (pre-booster) and 13 months (post booster):
1. hSBA GMTs 1 month after completion of primary immunisations for relevant Bexsero antigens: fHbp, NadA and PorA
2. hSBA proportions ≥1:4, at 1 month after completion of primary immunisations for relevant Bexsero antigens: fHbp, NadA and PorA

Key secondary outcome(s)
Local and systemic effects of the vaccine collected using a diary card completed for the 7 days following each set of vaccinations:
1. The percentage of infants presenting with fever, local reactions and non-febrile systemic reactions within the 7 days following each Bexsero® vaccine dose
2. The percentage of inpatients who have a change/deterioration in cardiorespiratory status within the 72 hours following each Bexsero® vaccine dose
3. The percentage of infants investigated for sepsis and commenced on antibiotics within 7 days of Bexsero® vaccination

4. hSBA GMTs at 12 months of chronological age (pre booster) for relevant Bexsero® antigens: fHbp, NadA and PorA
5. hSBA proportions ≥1:4, at 12 months of chronological age (pre booster) for relevant Bexsero® antigens: fHbp, NadA and PorA
6. hSBA GMTs at 13 months of chronological age (4-6 weeks post booster) for relevant Bexsero® antigens: fHbp, NadA and PorA
7. hSBA proportions ≥1:4, at 13 months of age (post booster) for relevant Bexsero® antigens: fHbp, NadA and PorA

Completion date
01/03/2020

Eligibility

Key inclusion criteria

1. Premature infant born at <35 weeks gestation
2. No contraindications to vaccination according to the ‘Green Book’
3. Willing and able to comply with study procedures
4. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Contraindication to vaccination according to the Green Book
2. Life-limiting congenital abnormality or condition
3. Prior diagnosis of an immunodeficiency syndrome
4. Considered unlikely to complete expected follow up until the end of the study

Date of first enrolment
01/08/2017

Date of final enrolment
01/10/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St George’s Hospital
Blackshaw Road
Tooting
United Kingdom
SW17 0QT

Study participating centre
John Radcliffe Hospital
Headley Way

Headington
United Kingdom
OX3 9DU

Study participating centre
Centre for Clinical Vaccinology and Tropical Medicine
Churchill Hospital
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United Kingdom
OX3 7LE

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
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NR4 7UY

Study participating centre
Queen Alexandra Hospital
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Study participating centre
Southampton General Hospital
Tremona Rd
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SO16 6YD

Study participating centre
Royal Cornwall Hospital
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TR1 3LQ

Sponsor information

Organisation
St George's, University of London

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Government

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Meningitis Now

Alternative Name(s)
Meningitis Trust, Meningitis UK

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	version v2.0	04/12/2017	10/07/2019	No	Yes
Protocol file	version V2.1	02/08/2018	10/07/2019	No	No