

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

Submission date 31/07/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/04/2021	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
acalvert@sgul.ac.uk
2. Jennifer Stuart
jstuart@sgul.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Anna Calvert

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Type(s)

Scientific

Contact name

Ms Jennifer Stuart

Contact details

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Additional identifiers**Clinical Trials Information System (CTIS)**

2017-001487-38

ClinicalTrials.gov (NCT)

Nil known

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

Study design

Randomised; Interventional; Design type: Prevention, Vaccine

Primary study design

Interventional

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 $\geq 1:4$, 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 $\geq 1:4$, 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 $\geq 1:4$, 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
Oxford
United Kingdom
OX3 7LE

Study participating centre

Norfolk and Norwich University Hospital

Colney Lane
Colney
United Kingdom
NR4 7UY

Study participating centre

Queen Alexandra Hospital

Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre

Southampton General Hospital

Tremona Rd
Southampton
United Kingdom
SO16 6YD

Study participating centre

Royal Cornwall Hospital

Treliske
Truro
United Kingdom
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)

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