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A study of immune responses to a booster dose of the licensed UK anthrax vaccine

Submission date
24/01/2019

Recruitment status
No longer recruiting

Registration date
15/04/2019

Overall study status
Completed

Last Edited
18/04/2019

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Anthrax is a disease caused by the bacterium Bacillus anthracis. Anthrax vaccine (known as AVP) provides protection for humans against subsequent exposure to Bacillus anthracis spores. The aim of this clinical study was to record immune responses to booster doses of the vaccine in two groups of healthy male and female subjects. Group A subjects were scheduled to receive their regular annual booster of AVP; Group B subjects had not received a dose of AVP for at least two years.

Who can participate?
Healthy adults aged 18 to 60 years.

What does the study involve?
The study involves all subjects receiving an anthrax vaccination following screening. The vaccine is given by intramuscular injection in the deltoid muscle of the upper arm. Blood samples were taken before dosing and at days 8, 15 and 29 after dosing. The final blood sample was taken at the end of study visit four months after the vaccination.

What are the possible benefits and risks of participating?
All the subjects who entered into this study received a licenced vaccine providing protection against anthrax. All medicinal products can on occasions cause unwanted effects, but in the study were no safety issues of clinical or statistical significance.

Where is the study run from?
Defence Science Technology Laboratory, Porton Down, Salisbury.

When is the study starting and how long is it expected to run for?
May 2009 to February 2013.

Who is funding the study?
The study was funded by UK MoD

Who is the main contact?
Defence Science Technology Laboratory, Porton Down, Salisbury,
Email- centralenquiries@dstl.gov.uk

Contact information

Type(s)
Scientific

Contact name
Dr Medical Advisor

Contact details
Defence Science Technology Laboratory, Porton Down
Salisbury
United Kingdom
SP4 0JQ

Additional identifiers

EudraCT/CTIS number
2005-004833-17

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Protocol number: CBD VP 132/05

Study information

Scientific Title
Assessment of the effect of prior anthrax vaccine precipitated (AVP) vaccination on the immune response to booster AVP vaccination: an open-label trial

Study objectives
To compare immune responses to a booster dose of the UK anthrax vaccine (AVP) in two groups of subjects with different prior booster dose regimens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/05/2009, Oxfordshire REC A Committee, ref: 09/H0604/14.

Study design

Interventional open label

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Possible occupational exposure to anthrax spores

Interventions
Generic drug name: Anthrax Vaccine Precipitated (AVP).

Dosage: One 0.5 mL dose of Anthrax Vaccine suspension for injection which contained not less than 0.125 mL of anthrax antigens.

Route of administration: intramuscular.

Duration of follow up: end of study visit was 120 days after the booster injection.

Intervention Type
Biological/Vaccine

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Anthrax vaccine suspension for injection

Primary outcome measure
Immune response is measured using analysis of blood sample at several time points up to 4 months after vaccination.

Secondary outcome measures
1. Safety and tolerability is measured using injection site assessments (conducted before, 30 minutes after dosing, and on days 8, 15, 29 and 120 after dosing.) Adverse events were checked on days 3, 8, 15, 29 after dosing. End of study visit included medical examination, vital signs and ECG.
2. Information on correlate of protection against anthrax was obtained from antibody levels from blood samples taken before dosing and on days 8, 15, 29, and 120 post- booster dose.

Overall study start date
07/09/2005

Completion date
22/04/2014

Eligibility

Key inclusion criteria
1. Aged between 18 and 60 years (inclusive)
2. Had, in the opinion of the investigator, completed a satisfactory primary series of AVP vaccination (four doses usually given at 0, 3, 6 and 32 weeks); individuals who had subsequently received one or more booster vaccinations could also be included
3. Eligibility to enter one of the following groups:
3.1. Group A: annual booster recipients (subjects scheduled to receive their annual booster of AVP - i.e. had their last dose 12 months ± one month previously)
3.2. Group B: delayed booster recipients (subjects who had not received a dose of AVP for at least two years).
4. Ability to communicate well with the investigator and to comply with the requirements of the study
5. Females of childbearing potential had to have a negative urinary pregnancy test at screening
6. Females of child-bearing potential had to use a reliable method of contraception (as agreed at the investigator's discretion) and agree to continue to do so from the screening visit until four weeks after the vaccination

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120 subjects

Total final enrolment
120

Key exclusion criteria
1. Presence of any clinically significant medical condition as determined by the investigator
2. Any clinically significant haematological or biochemical abnormality as determined by the investigator. Minor deviations outside the relevant reference range, in the absence of overt clinical disease, would not exclude a subject if it was considered that such findings would not affect the immune response to vaccination
3. Any surgical or medical condition which might significantly alter the immune response to the

vaccine, as determined by the investigator
4. Known or suspected hypersensitivity or idiosyncratic reaction related to any AVP vaccine components
5. History or evidence of regular alcohol intake of more than 28 units per week for men and 21 units per week for women, where 1 unit corresponds to 250 mL beer, 20 mL spirits/liqueur or one glass (100 mL) of wine
6. Participation in another clinical trial within the three months prior to dosing
7. Donation of blood or blood products within the three months prior to dosing, or the intention to donate blood or blood products during the course of the study
8. In the opinion of the investigator, had not received a satisfactory primary series of AVP vaccination (usually 0, 3, 6 and 32 weeks)
9. Received any other vaccination in the three weeks prior to dosing, or who required any vaccination within four weeks of the AVP vaccination

Date of first enrolment
02/05/2009

Date of final enrolment
22/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Defence Science Technology Laboratory
Porton Down
Salisbury
United Kingdom
SP4 0JQ

Sponsor information

Organisation
Defence Science and Technology Laboratory (Dstl)

Sponsor details
Porton Down
Salisbury
United Kingdom
SP4 0JQ

Sponsor type

Government

ROR
https://ror.org/04jswqb94

Funder(s)

Funder type
Government

Funder Name
Ministry of Defence

Alternative Name(s)
MOD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Our intention is to submit the results of this study for publication in an academic journal as soon as we have sufficient staff resources to prepare the manuscript.

Intention to publish date
10/04/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of subject consent being obtained at the time of the study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No