

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

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<b>Registration date</b> 15/04/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/04/2019	<b>Condition category</b> 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

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  $\pm$  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?
<a href="#">HRA research summary</a>			28/06/2023	No	No