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Our ref: FOI 2015/01888  
Your ref:

12 March 2015

Dear ' \_\_\_\_\_'

Thank you for your email of 17 February 2015 requesting the following information :

*"I would like to make a Freedom of Information request into the Trial conducted by \_\_\_\_\_ which the Dstl sponsored.*

*The trial was to look at the effects of Physostigmine and Hyoscine, the application is attached".*

We are treating your correspondence as a request for information under the Freedom of Information Act 2000 (FOIA).

A search for the information has now been completed within the Ministry of Defence, and we can confirm the following information in scope of your request is held.

For ease of reference, our responses are provided against each of your nine questions in turn below:

**Question 1.** "Did the trial go ahead ?"

**Answer 1.** We can confirm that the trial went ahead as approved.

**Question 2.** "How many volunteers took part in the study ?"

**Answer 2.** Fifty four volunteers took part in the trial; 37 were given active patches that contained both physostigmine and hyoscine and 17 were given placebo patches containing neither drug.

**Question 3.** "What dosage level was Physostigmine administered ?"

**Answer 3.** Volunteers in the group administered with active patches were given one patch, each containing both physostigmine (63.0 mg) and hyoscine (1.575 mg), every day for 21 days. Volunteers in the placebo group were given one patch (identical in appearance to active patches, but containing neither drug) every day for 21 days.

**Question 4.** “What dosage of Hyoscine was administered ?”

**Answer 4.** Please see the answer to Question 3 above.

**Question 5.** “If the clinical trial did not go ahead, why ?”

**Answer 5.** As indicated in the answer to Question 1 above, the trial went ahead as approved and was completed satisfactorily.

**Question 6.** “Did any volunteer suffer adverse effects, if so what combination of drugs were administered ?”

**Answer 6.** No volunteer suffered any adverse reaction to either drug.

**Question 7.** “Did any volunteer either administered the active drugs, or not, suffer from upper respiratory illnesses, if so what was the diagnosis and conclusion of the illness contracted ?”

**Answer 7.** One volunteer was reported to have had a mild, short-lived respiratory tract infection but this was not related to either of the study drugs administered.

**Question 8.** “Have any of the volunteers contacted your organisation or \_\_\_\_\_ to complain about side effects they suspect were caused by taking part in this trial ?”

**Answer 8.** Neither Dstl Porton Down nor \_\_\_\_\_ have been subsequently contacted by any of the volunteers who took part in this Clinical Trial, either to request any information about the trial or to make any health related complaints.

**Question 9.** “Have Dstl sponsored any other private sector organisations to conduct a similar trial involving both drugs.”

**Answer 9.** A Dstl sponsored clinical trial on patches containing physostigmine and hyoscine was carried out by a company named \_\_\_\_\_ in 2004.

If you are not satisfied with this response or you wish to complain about any aspect of the handling of your request, then you should contact me in the first instance. If informal resolution is not possible and you are still dissatisfied then you may apply for an independent internal review by contacting the Information Rights Compliance team, 1<sup>st</sup> Floor, MOD Main Building, Whitehall, SW1A 2HB (e-mail [CIO-FOI-IR@mod.uk](mailto:CIO-FOI-IR@mod.uk)). Please note that any request for an internal review must be made within 40 working days of the date on which the attempt to reach informal resolution has come to an end.

If you remain dissatisfied following an internal review, you may take your complaint to the Information Commissioner under the provisions of Section 50 of the Freedom of Information Act. Please note that the Information Commissioner will not investigate your case until the MOD internal review process has been completed. Further details of the role and powers of the Information Commissioner can be found on the Commissioner's website, <http://www.ico.gov.uk>

Yours sincerely

Dstl Secretariat