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The nuclear community charity fund chromosomal study

Submission date
24/01/2017

Recruitment status
No longer recruiting

Registration date
06/04/2017

Overall study status
Completed

Last Edited
04/10/2022

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The British Government undertook a series of atmospheric nuclear weapons tests at various sites in Australia and the South Pacific between 1952 and 1958. Associated with these tests was an experimental programme in which radioactivity was dispersed into the environment, this programme ended in 1963 although operations continued through to 1967. Additionally, UK personnel participated in a series of American tests based at Christmas Island in 1962. It is estimated that over 20,000 UK servicemen participated in at least one of these British and American tests.

An ongoing concern within the nuclear test community has been whether veterans of these programmes could have received sufficient radiation exposure to cause genetic damage (changes to the DNA) in them. Genetic damage can increase the risk of developing various diseases. This concern extends to whether they might also have passed on genetic alterations to their children, thereby potentially affecting their family's health.

The aim of this study is to determine whether there is any evidence of genetic alteration in veterans of historical nuclear test sites and/or their children when compared to control family groups.

Who can participate?
1. UK veterans who participated in nuclear testing programmes, their wives/partners and their children
2. UK veterans who did not participate in nuclear testing programmes but did serve in a tropical location, their wives/partners and their children

What does the study involve?
UK veterans are identified using military records and they and their wives/partners are invited to take part through receiving a letter from their GP practice. Interested veteran couples reply to the letter and receive a phone call to discuss the study and their eligibility. Participants are allocated to either the test group or the control group based on their military service and their participation in the nuclear testing programme. Veteran couples are then asked to give consent and to pass on an invitation letter and further information about the study to a child they have

had together. Veterans complete a brief telephone interview with the study team to discuss the details of their service, exposures to various things and a brief outline of their smoking and drinking habits. All participants (veteran, wife/partner and child) then go to their GP practice to have a small blood sample collected through placing a needle in a vein in their arm. The blood sample is sent for analysis. With each participant's explicit consent, the study team monitor all written and electronic medical records to assess their lifelong health. This information is obtained automatically by linking participant NHS number to various medical records, including those held by NHS Digital on cancer registrations and deaths and the Hospital Episodes Statistics database on hospital admissions.

What are the possible benefits and risks of participating?
Participants may benefit from clarifying the uncertainty about the possible health impact of participating in the nuclear testing programme in the past. Participants may experience discomfort during the collection of the blood sample.

Where is the study run from?
This study is run from the London School of Hygiene & Tropical Medicine (UK), Brunel University London (UK) and takes place in GP practices across the United Kingdom.

When is the study starting and how long is it expected to run for?
June 2016 to May 2022

Who is funding the study?
Armed Forces Covenant Aged Veterans Fund (UK)

Who is the main contact?
Dr Rhona Anderson

Contact information

Type(s)
Scientific

Contact name
Dr Rhona Anderson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v1

Study information

Scientific Title
Cytogenetic assessment of British nuclear test veterans and their families

Study objectives
To address whether there is a genetic legacy of participation at nuclear test sites the hypothesis are:
1. The frequency of chromosome aberrations detected in peripheral blood lymphocytes of a population of nuclear test veterans is significantly greater than that detected in a matched population
2. The spectra of chromosome aberrations detected in peripheral blood lymphocytes of a population of nuclear test veterans are significantly different from those in a matched population
3. The frequency of chromosome aberrations detected in peripheral blood lymphocytes of a population of 1st generation children is significantly greater than that detected in a matched population
4. The spectra of chromosome aberrations detected in peripheral blood lymphocytes of a population of 1st generation children are significantly different from those detected in a matched population

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Chelsea Research Ethics Committee, 24/02/2017, ref: 17/LO/0273

Study design
Observational case control study

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied
Not applicable

Interventions
Participants (both case and control groups) are identified using military records and are invited to participate through receiving a letter from their doctor's office.

If veterans and their wives/partners agree to participate they receive a telephone call to screen for interest and eligibility. The status of being allocated to the case group or the control group is confirmed during the telephone interview and is based on the participation in the nuclear testing programme and their service history. After giving informed consent they are asked to pass on the information sheet and consent form and study invitation to their offspring. Military veterans complete a short telephone call to collect details of their service and other potential clastogenic exposures. Participants give 17.5mL of blood, taken at their GP office, who then sends the blood to the Brunel University London laboratory. Using the fluorescence in situ hybridisation (FISH) based analysis, evidence of altered frequencies of chromosomal aberrations in veterans and/or in their children are compared to 50 control family groups. The study duration is three years.

All participants are flagged for lifelong follow-up through national registers for death and cancer registration and hospital admissions via Hospital Episode Statistics.

Intervention Type
Other

Primary outcome measure
Cytogenetic evidence of differences in the frequency and spectra of chromosome aberrations in male nuclear test veterans and/or their children is assessed using a range of chromosomal assays by taking a blood sample.

Secondary outcome measures
1. Future genetic and cytogenetic assessments of familiy groups will be assessed using stored DNA and isolated blood cells from blood samples
2. Long-term health status is followed up through national registers for death and cancer registration and hospital admissions via Hospital Episode Statistics

Overall study start date
01/06/2016

Completion date
31/05/2022

Eligibility

Key inclusion criteria
Intervention group:
1. UK residents

2. Registered with a UK GP
3. Contactable by phone
4. Must be a veteran born in 1930 or later who participated in the nuclear testing programme
4.1. Be the wife or partner of the veteran and be registered at the same GP as the veteran
4.2. Veterans and participating partner must have a surviving child together who is resident and willing to take part in the study

Control group:
1. UK residents
2. Registered with a UK GP
3. Contactable by phone
4. Must be a veteran born in 1930 or later who did not serve in the nuclear testing programme but did serve in a tropical location
4.1. Be the wife or partner of the veteran and be registered at the same GP as the veteran
4.2. Veterans and participating partner must have a surviving child together who is resident and willing to take part in the study

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
50 family trios for test and control groups

Total final enrolment
180

Key exclusion criteria
Veterans and participating children:
1. Been diagnosed with cancer (other than non-melanoma skin cancer)
2. Have had cytotoxic chemotherapy or radiation treatment for any reason (such as methotrexate for rheumatoid arthritis)

All participants:
1. Compromises the participant safety or compliance as judged by a GP

Date of first enrolment
01/04/2017

Date of final enrolment
01/03/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
London School of Hygiene and Tropical Medicine
Keppel St
London
United Kingdom
WC1E 7HT

Study participating centre
Brunel University London
Kingston Lane
Uxbridge
London
United Kingdom
UB8 3PH

Sponsor information

Organisation
Brunel University London

Sponsor details
Kingston Lane
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England
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UB8 3PH

Sponsor type
University/education

ROR
https://ror.org/00dn4t376

Funder(s)

Funder type
Not defined

Funder Name
Armed Forces Covenant Aged Veterans Fund

Results and Publications

Publication and dissemination plan
On completion of the study report, the main findings will be summarised and sent in a letter to those who participated in the study. Participants will also be able to access planned peer-reviewed publications in high-impact Journals reporting the results of the study. The study will be presented at nuclear community events and articles pertaining to the study results will be published in nuclear community publications.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/07/2022	06/07/2022	Yes	No
Results article		21/06/2022	04/10/2022	Yes	No
HRA research summary			28/06/2023	No	No