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Personalised cancer vaccines

Submission date 15/08/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/09/2016	**Overall study status** Completed	
Last Edited 28/09/2022	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Pancreatic cancer causes the uncontrolled growth of cells in a large gland of the digestive system. Pancreatic cancer has a very poor prognosis (forcast) with an overall survival rate of less than 5%. Current treatments are ineffective and even if the patient responds to initial treatments, relapse (the cancer coming back) is common due to the survival of small populations of resistant cancer cells. The immune system is capable of recognising and eliminating invading organisms by virtue of differences in their appearance when compared to normal components of the body. Cancer cells also have a different appearance compared to normal cells. However, these differences are often too small and weak to stimulate the immune system sufficiently to respond effectively to eliminate the tumour. The aim of this study is to analyse the small differences between healthy and cancer cells in pancreatic cancer patients by analysing genetic information from pancreatic cancer cells and see their ability to stimulate an immune response.

Who can participate?
Adults aged 17 to 66 who fulfill the NHS blood donation requirements.

What does the study involve?
Blood samples are taken from participants and are analysed for genetic information with respect to their ability to stimulate an immune response against cancer.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
1. NHS Blood and Transplant. Blood Donation Centre Edgware (UK)
2. NHS Blood and Transplant. Tooting Blood Donor Centre (UK)

When is the study starting and how long is it expected to run for?
August 2016 to July 2018

Who is funding the study?
Pancreatic Cancer Research Fund (UK)

Who is the main contact?
Professor Yaohe Wang

Contact information

Type(s)
Public

Contact name
Prof Yaohe Wang

Contact details
Charterhouse Square
London
United Kingdom
EC1M 6BQ

Additional identifiers

Protocol serial number
16/LO/1512

Study information

Scientific Title
Identification of immunogenic neo-epitopes for the development of personalised pancreatic cancer vaccines

Study objectives
Sequence analysis has allowed us to develop a peptide library of neo-epitopes that are expressed at high frequency in patient populations and have high binding affinities compared to their wild-type counterpart to HLA-A2, HLA-DP4, HLA-E*01:01 or HLA-*01:03 molecules. We hypothesise that a number of these will be sufficiently immunogenic to stimulate a T cell interferon-γ (IFN-γ) response in vitro, that will translate to an in vivo anti-tumour response. Immunogenic neo-epitopes can then be combined in a peptide vaccination program using adjuvants such as oncolytic viruses for targeted delivery and expression within tumours of PDAC patients to stimulate robust and long-term anti-tumour responses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Proportionate Review Sub-committee of the London - Westminster Research Ethics Committee, 10/08/2016, ref: 16/LO/1512

Study design
Observational

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Pancreatic cancer

Interventions
Peripheral blood mononuclear cells (PBMCs) obtained from leukocyte filters from healthy individuals will be HLA typed using commercially available reagents from thermofisher scientific. HLA-A2, HLA-DP4, HLA-E*01:01 and/or HLA-E*01:03 positive samples will be pulsed with peptides selected after bioinformatics analysis of available sequence data. IFN-γ and interleukin-2 (IL-2) production by the T cells in the samples will be evaluated by ELISA after two rounds of stimulation within a two weeks time as a measure of peptide immunogenicity. Once immunogenic peptides have been identified, their wild-type counterparts will be analysed in parallel to confirm specificity for the mutated epitope. Immunogenic peptides whose wild-type counterparts do not elicit immune responses will then be selected for inclusion in an oncolytic virus-based vaccine to be analysed in vivo using transgenic HLA-A2/HLA-DP4 mice.

Intervention Type
Other

Primary outcome(s)
Immunogenicity of neo-epitope candidates selected from available mutanome data using peripheral blood mononuclear cells (PBMCs) from healthy individuals.

Key secondary outcome(s))
N/A

Completion date
20/07/2018

Eligibility

Key inclusion criteria
Individuals who fulfill the NHS BT requirements for blood donation, which are:
1. fit and healthy
2. weigh over 7 stone 12 lbs or 50kg
3. are aged between 17 and 66 (or 70 if you have given blood before)
4. are over 70 and have given blood in the last two years

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Key exclusion criteria
Same as NHS BT criteria, which are:
1. receiving treatment
2. taking medication
3. travelling outside of the UK
4. tattoos
5. pregnancy
6. illness
7. cancer
8. received blood, blood products or organs

Date of first enrolment
01/08/2016

Date of final enrolment
20/07/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NHS Blood and Transplant. Blood Donation Centre Edgware
Edgware Community Hospital
Burnt Oak Broadway
Edgware
Middlesex
United Kingdom
HA8 0AD

Study participating centre
NHS Blood and Transplant. Tooting Blood Donor Centre
75 Cranmer Street
Tooting
London
United Kingdom
SW17 0RB

Sponsor information

Organisation
Joint Research Management Office, Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Pancreatic Cancer Research Fund

Alternative Name(s)
PCRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
-

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/05/2022	28/09/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes