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Vaccination with Adjuvants, Peptides and Elimination of Regulatory Cells: Enhancement of the body's anticancer immunity by vaccination

Submission date 17/12/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 29/01/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 29/03/2018	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-using-a-vaccine-and-chemotherapy-to-treat-advanced-cancer-vaper

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2014-003025-18

Protocol serial number

01; 117895

Study information

Scientific Title
In vitro generation of optimal tumour antigen-specific anticancer immune responses, by vaccination with Human Telomerase Reverse Transcriptase (HTERT) peptides, in combination with specific adjuvants and elimination of immunosuppressive regulatory cells, in patients with advanced cancer

Acronym
VAPER

Study objectives
Vaccination with HTERT peptides in combination with specific adjuvants and elimination of regulatory suppressor cells can enhance anticancer immune responses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - London Bridge Research Ethics Committee, 08/05/2015, REC ref: 15/LO/0117

Primary study design
Interventional

Study design
Single-centre open-label fixed-dose comparative study

Study type(s)
Prevention

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

Interventions
Patients are randomly allocated to either Group A or Group B.

All patients (groups A and B) will receive eight intradermal injections of 2 ml, consisting of 700ug of HTERT peptides in 1 ml normal saline (NS) mixed with Montanide ISA-51 VG,1 ml, given at 3 weekly intervals.

Topical Imiquimod 12.5 mg will be applied by the patient to the vaccination site day 1-5 post vaccination.

All patients (groups A and B) will receive a 10 day course of low dose oral Cyclophosphamide day 1-10 of each vaccination cycle.

Group B patients will take Celecoxib 400mg bd PO daily for the duration of the trial.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Human Telomerase Reverse Transcriptase (HTERT) peptides, cyclophosphamide

Primary outcome(s)
To establish that the study is safe, well tolerated and patient acceptable.

Patients wil be asked to complete validated questionaires (Mood Rating Scale, Hospital Anxiety and Depression Scale, Patient Attitude to Treatment Scale, FACT-Biological Response Modifiers) prior to treatment, at each vaccination visit and 4 weeks after the final vaccination. The forms will be evaluated and statistically analysed by Chi square and Fisher's exact tests at the end of treatment.

Morbidity, side effects of treatment, will be documented at each clinic visit. Serious adverse events (SAEs) and sudden unexpected serious adverse reactions (SSUSARs) will be documented if and when they occur.

Key secondary outcome(s)
The generation of specific anticancer immunological responses and objective evidence of clinical responses during the programme.

Blood will be taken for assessment of immunological parameters prior to treatment, at each vaccination visit and 4 weeks after the end of treatment. Tumour markers, if present, will also be monitored at each visit and documented.

Reduction or stasis of tumour volume will be recorded at each visit if there is measureable tumour.

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Age 18-85, either sex
2. Histologically or cytologically proven cancer
3. No further beneficial anticancer therapy available
4. Completed treatment at least 4 weeks previously
5. Post menopausal or sterilised or practising contraception
6. WHO status 3 or less
7. Life expectancy at least 30 weeks
8. Ability to give informed written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
All

Key exclusion criteria
1. Pregnancy, lactation
2. Men and premenopausal women unwilling to practise reliable contraception
3. Inability to give informed written consent
4. Cerebral metastasis
5. Autoimmune disorders
6. Undergoing immunosuppressive therapy
7. Cardiovascular disease:coronary artery disease,major cardiac disease [left ventricular ejection fraction (LVEF <50%)], poorly controlled hypertension
8.Peptic ulceration,inflammatory bowel disease
9. Allergy to nonsteroidal anti-inflammatory drug (NSAID) therapy, celecoxib, asthma or allergy following aspirin
10. Allergy to sulphonamides
11. Past history of stroke or transient ischaemic attacks

Date of first enrolment
04/02/2013

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham University Hospitals NHS Trust
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

Organisation
King's College Health Partners Clinical Trials Office

Organisation
Nottingham University Hospitals NHS Trust

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Charity

Funder Name
Candles Charity (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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