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Autologous TLPLDC vaccine (tumor lysate, particle loaded, dendritic cells)

Submission date	Recruitment status	[_] Prospectively registered
15/02/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/02/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/11/2018	Cancer	

Plain English summary of protocol
Background and study aims
The aim of this study is to determine the safety and effectiveness of a vaccine, made from the patient's own tumor tissue and blood, to prevent cancer recurrence in patients with solid tumors.

Who can participate?
Patients aged over 18 with solid tumors

What does the study involve?
Tumor tissue is collected during standard of care surgery along with a blood sample. The vaccine (prepared from components of the tumor and the blood) is given for a total of four times over a period of three months. The patient will continue to see their treating medical oncologist for standard of care follow up. Any adverse events and tumor response are assessed at each study visit and standard of care visit.

What are the possible benefits and risks of participating?
Patients may develop an immune response that may prevent recurrence of cancer or treat an existing tumor.

Where is the study run from?
Perseus Cayman Limited (Cayman Islands)

When is the study starting and how long is it expected to run for?
November 2012 to January 2018

Who is funding the study?
Perseus PCI (USA)

Who is the main contact?
Dr George Peoples

Contact information

Type(s)
Scientific

Contact name
Dr George Peoples

Contact details
110 E. Houston Street
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78205

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Autologous TLPLDC vaccine (tumor lysate, particle loaded, dendritic cells): a single-arm open-label trial

Study objectives
Autologous TLPLDC vaccine prevents recurrences in resected stage III/IV or to treat stage IV solid tumors

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cayman Island Health Practice Commission, 25/01/2013, registration number: HPC/HCF/129

Study design
Single-arm open-label interventional

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Resected stage III/IV solid tumor or to stage IV solid tumors

Interventions
A vaccine is made from the patient's own tumor tissue (collected during standard of care surgery) and blood. Patients will be seen for a total of four months to receive the initial vaccine and then three follow up visit vaccine inoculations (1/month). Safety and efficacy will be assessed for each patient. Follow up will be continued as per standard of care dictated by the patient's treating medical oncologist for a continual assessment of disease free status/tumor response and any adverse events. This information will be collected from the electronic medical record. Patients will be followed up to 2 years for disease progression and overall survival.

Intervention Type
Biological/Vaccine

Primary outcome measure
Safety of of the autologous TLPLDC vaccine at baseline, month 1, 2, 3 and at each standard of care visit to the treating medical oncologist. Safety data will be collected on local and systemic toxicities and graded and reported per the Common Terminology Criteria for Adverse Events (CTCAE) v4.03.

Secondary outcome measures
Efficacy of the autologous TLPLDC vaccine at baseline, month 1, 2, 3 and at each standard of care visit to the treating medical oncologist. Disease-free status/tumor response will be monitored per standard of care as dictated by the patients' treating medical oncologist. This information will be obtained from the patient and/or the referring medical oncologist. Follow-up scans will be assessed for tumor response per RECIST v1.1.

Overall study start date
26/11/2012

Completion date
01/01/2018

Eligibility

Key inclusion criteria
1. Stage III/IV (resected) solid tumor malignancy
2. Stage IV solid tumor malignancy with accessible tumor
3. Approximately 1 mg (1 cm3) of accessible and dispensable tumor that will not interfere with pathologic staging
4. ECOG 0-1 performance

5. Not involved in other clinical trials
6. Capable of giving informed consent
7. Age 18 to 99

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. ECOG >2
2. Insufficient tumor available to produce vaccine
3. Immune deficiency disease or HIV, active HBV, or active HCV
4. Steroids or other immunosuppressants

Date of first enrolment
26/11/2012

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
Cayman Islands

Study participating centre
Perseus Cayman Limited
Cayman Islands
KY1-1206

Sponsor information

Organisation
Perseus PCI (USA)

Sponsor details
7901 Dadiva Ct
Austin
United States of America
78735

Sponsor type
Industry

Website
www.perseuspci.com

ROR
https://ror.org/03mfyst18

Funder(s)

Funder type
Industry

Funder Name
Perseus PCI (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/01/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/05/2018		Yes	No