

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

Submission date 15/02/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/02/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/11/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

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
San Antonio
United States of America
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