Evaluation of V*9Vδ2-T cells in the peripheral blood of patients with metastatic castrationresistant prostate cancer

Published: 15-05-2024
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To investigate the frequency of V*9Vδ2-T cells in patients with metastatic castration-resistant prostate cancer

Ethical review	Approved WMO
Status	Completed
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON56769

Source
ToetsingOnline

Brief title
LAVA_GD-01_metastatic castrationresistant prostate cancer

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
mCRPC, Prostate Cancer

Research involving
Human

Sponsors and support

Primary sponsor: LAVA Therapeutics NV
Source(s) of monetary or material Support: LAVA Therapeutics NV

Intervention

Keyword: prostaatkanker

Outcome measures

Primary outcome

To investigate the frequency of Vγ9Vδ2-T cells in patients with metastatic

castration-resistant

prostate cancer.

Secondary outcome

To investigate any correlations between the frequency of Vγ9Vδ2-T cells and

clinical

characteristics.

To investigate any correlations between the frequency of Vγ9Vδ2-T cells and

treatment history.

Study description

Background summary

LAVA Therapeutics is developing a platform of bispecific antibodies that target and employ V*9Vδ2-T cells as effector cells. V*9Vδ2-T cells make up approximately 1-5% of all CD3+ T cells in the peripheral circulation of healthy individuals and have a critical role in immune surveillance with an ability to detect and target tumor cells (Lo Presti et al. 2017; de Weerdt et al. 2018; Kunzmann et al.1999; Gertner-Dardenne et al. 2012). The presence of V*9Vδ2-T cells in blood and solid tumors correlates with favorable outcomes highlighting their importance (Gentles et al., 2015, Tosolini et al., 2017). However, levels of V*9Vδ2-T cells may vary between cancer patients. This study aims to understand the distribution of V*9Vδ2-T cells and any factors that influence V*9Vδ2-T frequency.

Study objective

To investigate the frequency of V*9Vδ2-T cells in patients with metastatic castration-resistant prostate cancer

Study design

A single blood collection during a single visit will be obtained from eligible patients to assess Vγ9Vδ2-T cell frequency. Demographics, treatment history, disease history and clinical characteristics will be collected to examine any correlations with Vγ9Vδ2-T cell frequency. No investigational medicinal product (IMP) will be administered in this study. The study is for research purposes only, and data is not intended to be used for facilitating or informing any clinical or treatment decisions.

Study burden and risks

Patient demographics, clinical characteristics, treatment history, and disease history will be collected.
A single blood sample will be collected during a single visit.
Patients will not be followed up.

Contacts

Public
LAVA Therapeutics NV

Yalelaan 62
Utrecht 3584 CM
NL
Scientific
LAVA Therapeutics NV

Yalelaan 62
Utrecht 3584 CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients are eligible to be included in the study only if all of the following criteria apply:
1. Patient must be 18 years of age or above at the time of signing the informed consent.
2. Male patient with mCRPC (histologically confirmed adenocarcinoma of the prostate) as defined by
Prostate Cancer Working Group 3 (PCWG3) criteria.
3. Patient should have received at least 2 lines of prior therapy in the mCRPC setting, including at least one
androgen receptor pathway inhibitor (e.g., abiraterone, enzalutamide). Patients may or may not have
received a taxane-based chemotherapy. Taxane-naïve patients will not exceed 20% of all patients enrolled. Patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutations should have received a Poly-ADP ribose polymerase (PARP) inhibitor.

Exclusion criteria

Patients are excluded from the study if any of the following criteria apply:
1. Uncontrolled or severe intercurrent medical condition.
2. Adenocarcinoma with small cell or neuroendocrine features.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	13-08-2024
Enrollment:	50
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	15-05-2024
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-08-2024
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86570.056.24