Preparation of AKT-DC from Lymph nodes derived through Surgery and Endobronchial ultrasound guided biopsy in non-small cell lung cancer patients.

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To assess whether procedures and techniques used to derive AKT-DC out of lymph node material influences the quality and number of the AKT-DC end-product.

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON51383

Source
ToetsingOnline

Brief title
PALSE-study

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer, Non-small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Antikankerfonds België

Intervention

Keyword: AKT-DC, Endobrochial ultrasound (EBUS), NSCLC, Surgery

Outcome measures

Primary outcome

1. To assess the feasibility of transposing Bioaccell AKT-DC manufacturing protocol as used by Kimura et al. to the Erasmus MC (EMC).

2. To optimize the generation of AKT-DCs from cytological specimens (EBUS-FNAs of hilar and mediastinal lymph nodes).

3. Validate production in a relevant study population.

4. Provide necessary documentation to submit a phase 1 clinical trial for approval [investigational medicinal product dossier (IMPD), investigator brochure, etc] in the most relevant and feasible clinical setting.

5. To gain a deeper understanding of the mode of action and therapeutic potential of AKT-DCs by performing a comprehensive analysis of cellular subsets and immunoreactivity within tumor-draining lymph nodes of NSCLC patients.

Secondary outcome

NA

Study description

Background summary

The introduction of the immune checkpoint inhibitors anti-programmed cell death 1 (PD-1)/programmed cell death ligand 1 (PD-L1) revolutionized the treatment of non-small cell lung cancer (NSCLC), yet some patients are refractory to treatment and new immunotherapies are under investigation. Autologous expanded cells from tumour draining lymph nodes (TDLNs), the activated killer T cells and dendritic cells (AKT-DC), together with adjuvant chemotherapy have been

shown to increase survival of resected primary lung cancer patients. To generate the AKT-DC, lymph nodes can be obtained during surgery for resectable stage I-III patient, yet surgery is not indicated for stage IV patients. For these patients, cytological specimens (endobronchial ultrasound (EBUS)-fine needle aspirates (FNAs) of hilar and mediastinal lymph nodes) can be used to obtain lymph node material.

Study objective

To assess whether procedures and techniques used to derive AKT-DC out of lymph node material influences the quality and number of the AKT-DC end-product.

Study design

Preclinical study to assess the feasibility to culture a lymph node derived therapeutic cell product.

Study burden and risks

For unresectable NSCLC patients this study design requires additional EBUS passes from suspicious lymph nodes as well as EBUS from non-suspicious lymph nodes and non-tumor draining lymph nodes which need to be specifically collected for this research proposal. For both resectable and stage IV NSCLC, the cultures will also require an additional peripheral blood draw. This consists in 1-2 × 109 peripheral blood lymphocytes (PBL) obtained by lymphocyte apheresis.
This preclinical study serves to prepare a subsequent clinical trial. None of the cultured cells will therefore be administered to the patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Age >=18 years.
• Able to understand the written information and able to give informed consent according to International Conference of Harmonisation (ICH)/ Good Clinical Practice (GCP).
• Histologically or radiologically-proven diagnosis of NSCLC.

Exclusion criteria

- Unable to receive extra-additional passes during EBUS and/or to undergo lymphocyte apheresis.
- Pregnant or lactating
- Subject with any known active serious infection, including human immunodeficiency
virus (HIV), hepatitis B or C virus, or syphilis infection.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-06-2022
Enrollment:	8
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-07-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL79806.078.22