Improving Standard of Care lifestyle support for stage III NSCLC cancer patients

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By an early-initiated personal, supportive care program prevent deterioration of performance status (=WHO 0 or 1) in at least 90% of patients with NSCLC stage III, as determined by the patient itself, at the start of immunotherapy.

Ethical review	Not approved
Status	Will not start
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON53651

Source
ToetsingOnline

Brief title
PERCUSSION

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
Lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: MAASTRO clinic
Source(s) of monetary or material Support: Astra Zeneca

Intervention

Keyword: Durvalumab, Lifestyle, Lung Cancer

Outcome measures

Primary outcome

Sustained good performance status (=WHO 0 or 1) in at least 90% of the

patients, as determined by the patient itself, at the start of immunotherapy.

Secondary outcome

- % patients successfully adhering to the dietary, exercise, smoking advice

- % grade 3 dysphagia and odynophagia

- % grade 2 dyspnea

- % hospitalization for (treatment-related) complications (from start until 6

weeks after radiotherapy)

- Difference between proton and photon therapy

- % patients receiving durvalumab

- Quality of life

Study description

Background summary

In inoperable Stage III Non-Small Cell Lung Cancer (NSCLC), consolidation immune checkpoint inhibition with the PD-L1 inhibitor durvalumab, given within 6 weeks after completion of concurrent platinum-based chemoradiotherapy (CCRT) for 12 months results in remarkable improvement of 5-year overall survival rates (42.9 % vs 33.4%). This tri-modal therapy has become the new standard of care. Unfortunately, the tri-modal therapy causes frequently adverse events such as fatigue, and to a much lesser degree cough, dyspnea and pneumonitis (3), resulting in treatment cessation in 15% - 53% of the patients. For the most optimal overall survival (OS) and disease-free survival (DFS), compliance to the full treatment regimen, i.e., in the ideal situation 100% of patients

completing their full course of CCRT and receiving durvalumab for one year, is expected to have significant and relevant beneficial effects. Optimizing patients* fitness is essential to handle the burden of the full treatment regimen.

Study objective

By an early-initiated personal, supportive care program prevent deterioration of performance status (=WHO 0 or 1) in at least 90% of patients with NSCLC stage III, as determined by the patient itself, at the start of immunotherapy.

Study design

Prospective, non-randomized observational non-interventional clinical trial. Patients will receive standard of care in combination with a supportive, personalized program regarding smoking, diet and exercise.

Study burden and risks

The risks of participating in the trial for the patients are very small.
The burden consists mainly of the time it will cost patients with filling out questionnaires and dietary- and physical activity records.
During treatment, patients* physical condition may improve due to the lifestyle intervention, making it easier to undergo the radiation and immunotherapy treatment.

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

• Pathological diagnosis of adequately staged (according to standard practice using chest-CT, FDG-PET, brain imaging MRI/CT) NSCLC
• Participant is willing and able to give informed consent for participation in the trial
• Aged 18 years or above
• Scheduled to receive one of the following two therapeutic strategies:
o Concurrent chemotherapy and radiotherapy with photons (60 Gy in 30 fractions of 2 Gy) followed by durvalumab in patients with stage III NSCLC
o Concurrent chemotherapy and radiotherapy with protons (60 Gy in 30 fractions of 2 Gy) followed by durvalumab in patients with stage III NSCLC
• Is able and willing to comply with all trial requirements

Exclusion criteria

- Mixed non-small cell lung cancer with other histology such as small cell lung cancer
- Not able to comply with the study protocol
- Less than 18 years* old
- Pregnancy or not able to comply with adequate contraception in women with child baring potential
- Previous radiotherapy to the chest for benign or malignant conditions, including radiation for breast cancer
- Previous malignancies treated within 2 years before inclusion in the present study, except for any in situ cancer or non-melanoma skin cancer when radically treated

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Not approved

Date:	18-07-2023
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
ClinicalTrials.gov	NCT05287971
CCMO	NL81220.096.23