The effect of smoking status on the treatment of non-small cell lung cancer with immunotherapy

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Mortality will be lower in patients who do not smoke during treatment of non-small cell lung carcinoma with PD-L1-inhibitors compared to patients who smoke during their treatment with PD-L1-inhibitors.

Ethical review	Positive opinion
Status	Suspended
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON29412

Source
Nationaal Trial Register

Brief title
SOCCER

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Health condition

non-small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: inapplicable

Source(s) of monetary or material Support: inapplicable

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

1) Mortality 2) Progression free survival

Secondary outcome

1) Adverse effects 2) Percentage of smokers that stops smoking during treatment 3) Percentage of smokers who attempt to quit smoking during treatment 4) Percentage of former/never smokers who (re)start smoking during treatment

Study description

Background summary

Lung cancer remains the number one in cancer related deaths around the globe. In the year 2020 there were 2.2 million diagnoses of lung cancer world wide and 1.8 million lung cancer related deaths (Sung et al., 2021). An upcoming treatment of lung cancer is immunotherapy, more specifically programmed death ligand-1 (PD-L1) inhibitors. It has traditionally been known that in lung cancer it is important to cease smoking, because smoking has a negative influence on the success of treatment with chemotherapy and radiotherapy. Surprisingly, a recent meta-analysis showed that lung cancer treatment with PD-L1 inhibitors was more effective in patients who smoke or used to smoke compared to patients who never smoked (Mo et al., 2020). This raises the question of what the effect is of smoking during treatment with PD-L1 inhibitors compared to not smoking during the treatment. The aim of our study is to gain more insights regarding this question. The study will consist of a retrospective and a prospective part. The retrospective part will consist of a file study of all patients from 2018 treated for non-small cell lung carcinoma with immunotherapy and/or chemotherapy. The prospective part consists of patients diagnosed with non-small cell lung cancer who receive treatment from July 2021 until September 2022. These patients will be approached by their physician to take part in our study. The participating patients will have to fill in a questionnaire about their smoking status at the point of inclusion and after every 8 weeks. After the second questionnaire patients will have the choice to stop filling in questionnaires if they believe their smoking status is not going to change during their treatment. The data from the questionnaires will be combined with a file study which assesses among other

things their side effects, progression free survival and mortality. The acquired data will be assessed using a variety of statistical tests. References Mo, J., Hu, X., Gu, L., Chen, B., Khadaroo, P. A., Shen, Z., . . . Liu, J. (2020). Smokers or non-smokers: who benefits more from immune checkpoint inhibitors in treatment of malignancies? An up-to-date meta-analysis. World J Surg Oncol, 18(1), 15. doi:10.1186/s12957-020-1792-4 Sung, H., Ferlay, J., Siegel, R. L., Laversanne, M., Soerjomataram, I., Jemal, A., & Bray, F. (2021). Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. doi:10.3322/caac.21660

Study objective

Mortality will be lower in patients who do not smoke during treatment of non-small cell lung carcinoma with PD-L1-inhibitors compared to patients who smoke during their treatment with PD-L1-inhibitors.

Study design

There are at least 2 time points in the prospective part of the study. The first time point is at the time of inclusion, this is when they fill in the first questionnaire . The second time point is after 8 weeks.

Intervention

inapplicable

Contacts

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Eligibility criteria

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

Inclusion criteria

All patients older than 18 years old diagnosed with non-small cell lung cancer treated with immunotherapy and/or chemotherapy.

Exclusion criteria

Patients younger than 18 years old or patients incapable of filling in the questionnaire.

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	05-07-2021
Enrollment:	607
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-05-2021
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
NTR-new	NL9794
Other	METC Z : METCZ20210079

Study results