De invloed van rookstatus op de behandeling van longkanker met immunotherapie

Gepubliceerd: 15-10-2021 Laatst bijgewerkt: 09-05-2024

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.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	Ademhalingsorgaan- en mediastinale neoplasmata maligne en niet-gespecificeerd
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29412

Bron
NTR

Verkorte titel
SOCCER

Aandoening

- Ademhalingsorgaan- en mediastinale neoplasmata maligne en niet-gespecificeerd

Aandoening

non-small cell lung cancer

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: inapplicable

Overige ondersteuning: inapplicable

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

1) Mortality 2) Progression free survival

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

inapplicable

Contactpersonen

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend
Doel:	Preventie

Deelname

Nederland
Status: Werving tijdelijk gestopt

(Verwachte) startdatum:	05-07-2021
Aantal proefpersonen:	607
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-05-2021
Soort:	Eerste indiening
Toetsingscommissie:	METC Z: Zuyderland-Zuyd (Heerlen)

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9794
Ander register	METC Z : METCZ20210079

Resultaten