Prediciting Radiation-Induced lung injury through patient-specific lung epithelial ORganoids

Gepubliceerd: 24-12-2020 Laatst bijgewerkt: 18-08-2022

Radiation side-effects can be predicted by irradiating patient specific lung epithelial organoids in vitro.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26284

Bron
NTR

Verkorte titel
PRIOR

Aandoening

Stage III NSCLC

Ondersteuning

Primaire sponsor: NA
Overige ondersteuning: LUMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

A significant difference in the number of yH2AX foci (double strand DNA damage) per cell

induced by in vitro radiation between
patient-specific normal epithelial cells from patients with grade 2 or higher pneumonitis or fibrosis following chemoradiation or proton
therapy based on CTCAE scoring system and patients with grade 1 or lower pneumonitis or fibrosis.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:
Standard of care for patients with stage III non-small cell lung cancer (NSCLC) is chemotherapy combined with concurrent or
sequential radiotherapy. Radiation-induced lung injury (RILI) of normal lung tissue is one of the main dose-limiting factors during
radiation treatment. Therefore, it is important to identify which patients are at risk for RILI to be able to create a personalized
radiation treatment and prevent reduction in quality of life (QOL) in cancer survivors. So far, no reliable biomarkers have been found
that can be used for this identification. This study aims to use patient-derived airway epithelial organoids to search for individual
predictors for RILI.

Objective of the study:
To demonstrate the validity of using patient-derived lung epithelial organoids, as a model of normal lung tissue, we aim to assess
lung epithelial cell responses to ionizing radiation exposure and relate these to clinical outcome. In addition, clinical outcome
parameters will be combined to create a better understanding of RILI.
Study design: This study is a prospective cross-sectional study.

Doel van het onderzoek

Radiation side-effects can be predicted by irradiating patient specific lung epithelial organoids in vitro.

Onderzoeksopzet

3, 6, and 12 months

Onderzoeksproduct en/of interventie

Bronchoalveolar lavage

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age > 18-85 years;
• Clinical suspicion of lung tumor with mediastinal lymph node involvement based on enlarged lymph nodes on CT
thorax or FDG uptake on PET-CT conform ESMO guidelines;
• Planned bronchoscopy with endobronchial ultrasound (EBUS) with sedation (Propofol or benzodiazepine) for
standard diagnostic work -up;
• Clinical performance adequate for undergoing EBUS (according to pulmonary physician ordering the diagnostic
procedure).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Clinical performance too low to undergo EBUS according to pulmonary physician ordering the diagnostic
procedure;
• Suspicion of metastasis or stage IV disease on PET-CT or CT-thorax;
• Inadequate understanding of the Dutch language in speech and writing.

• Clinical performance too low to receive chemoradiotherapy or proton therapy;
• Significant co-morbidities such as end stage renal disease, severe cardiovascular disease, severe psychiatric
disease, end stage COPD, or other comorbidity with limited expected survival (<1 year) or WHO performance
status >3;
• Known pre-existent diagnosis of lung fibrosis or newly diagnosed lung fibrosis before start of the study;
• Previous thoracic radiation-treatment.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-01-2021
Aantal proefpersonen:	65
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-12-2020
Soort:	Eerste indiening

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	NL9142
Ander register	METC LDD : P20.070

Resultaten