Qualification of imaging methods to assess cancer drug induced interstitial lung disease (ImageILD)

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON46831

Source
ToetsingOnline

Brief title
EORTC-1658-IG

Condition

- Bronchial disorders (excl neoplasms)

Synonym
DIILD

Research involving
Human

Sponsors and support

Primary sponsor: European Organisation for Research in Treatment of Cancer (EORTC)

Source(s) of monetary or material Support: EORTC,Innovative Medicines Initiative Joint Undertaking

Intervention

Keyword: DIILD (drug induced interstitial lung disease), imaging methods

Outcome measures

Primary outcome

-Relative change of FVC between study entry (DIILD diagnosis) and 6 weeks after

diagnosis (treatment adaptation)

- Relative change in the semi-quantitative radiology scores between study entry

(DIILD diagnosis) and 6 weeks after diagnosed DIILD (treatment adaptation)

Secondary outcome

To be evaluated at study entry, at 6 weeks and 6 months:

* FVC

* Other pulmonary physiology results (e.g. DLCO and 6MWT)

* Respiratory patient report outcome

* Quality of life

To be evaluated at study entry and at 6 weeks:

* Radiology qualitative analysis (3 grading)

* Quantitative volumetric inspiratory CT measurements

Study description

Background summary

Drug induced interstitial lung disease (DIILD) is caused by iatrogenic injury to the lung parenchyma and can be caused by over four hundred different drugs in humans. The incidence of DIILD in modern oncology practice is unknown but

available evidence suggests that this is underdiagnosed worldwide. The incidence of DIILD has increased in the past 15 years, and is predicted to continue to rise with the advent of new generation anti-cancer drugs where the risk of lung injury is seldom recognized during early drug development. Clinical manifestations range from mild to severe and progressive. In its more severe form, DIILD may result in acute respiratory distress syndrome, respiratory failure and death. Early recognition of DIILD is important because lung injury can be reversed if appropriate therapy is instituted soon after the onset of symptoms.

Study objective

The primary objective of the study is to qualify an objective semi-quantitative CT scoring system looking
at the correlation between the relative change in the semi-quantitative CT score from baseline to week 6
after DIILD diagnosis and the relative change in FVC from baseline to week 6 after DIILD diagnosis.

Study design

multicenter, multinational
non-randomized, non-drug
patients will be followed for 6 months from diagnosis of DIILD, data will be collected, patients will undergo questionnaires, CT's, blood draws, pulmonary function tests

Study burden and risks

Burden in time is that patients undergo extra assessments, but these are usually not burdensome for the patients (non-burdensome questionnaires, CT-chest, pulmonary function tests)
Risk: the questionnaires are non-burdensome, radiation of a chest CT is neglible nowadays, patient can get dizzy from a pulmonary function test. Blood draws can cause a hematoma, this can be uncomfortable for the patient.

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
* WHO performance status 0-2
* Life expectancy > 6 months
* Proven cancer diagnosis in a patient actively undergoing systemic anticancer therapy
* New onset symptoms (e.g. cough, fever, dyspnoea, and hypoxia) at any time during or within 4 weeks of the last dose of anti-cancer treatment
* New onset radiological (CXR or CT) abnormalities within the lungs at any time during or within 4 weeks of the last dose of anti-cancer treatment (e.g. diffuse lung changes, infiltrative opacification in the periphery of the lung or ground glass changes) with a locally reviewed diagnosis of DIILD as the most likely explanation for the radiological abnormalities.
* Treatment for DIILD planned (e.g. drug withdrawal, interruption +/- supportive therapy including corticosteroids, oxygen, bronchodilators etc.). Treatment with antibiotics, anticoagulants etc. is permitted pending results of investigations for differential diagnoses.
* Able to undergo pulmonary function tests (at a minimum spirometry and gas transfer (DLCO))
* Patients enrolled on other anti-cancer investigational trials are permitted at investigator discretion
* Informed written consent obtained according to ICH/GCP, and

national/local regulations
* Women of child bearing potential (WOCBP) must have a negative serum (or urine) pregnancy test within 14 days before study registration

Exclusion criteria

* Primary lung tumor greater than 3cm
* Lung metastatic lesion > 2cm or greater than 5 metastases
* Claustrophobia, or inability to undergo non-contrast CT examination
* Known or suspected non-drug related ILD (e.g. lung abnormalities due to other causes such as occupational exposure)
* Previous thoracic lobectomy
* Clinical, radiological or microbiological evidence of active lower respiratory tract infection
* Currently active, clinically significant heart disease, such as uncontrolled class 3 or 4 congestive heart failure defined by the New York Heart Association Functional Classification
* Any medical, psychological, sociological or geographical condition that could affect participation in the study and compliance with the study protocol

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	5
Type:	Anticipated

Ethics review

Approved WMO Date:	17-04-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCTnumber03294746
CCMO	NL64729.068.18