

Intrapulmonal nintedanib distribution in fibrotic interstitial lung disease patients: drug concentrations in lung explantates

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21428

Source

NTR

Brief title

MONTE CARLA study

Health condition

Interstitial lung disease

Sponsors and support

Primary sponsor: Erasmus MC dept. of Medical Oncology and dept. of Pulmonology

Source(s) of monetary or material Support: Erasmus MC dept. of Medical Oncology and dept. of Pulmonology

Intervention

Outcome measures

Primary outcome

Penetration rate of nintedanib in different types of lung tissue.

Secondary outcome

Variability in nintedanib concentrations

Study description

Background summary

Nintedanib is a small-molecule kinase inhibitor used for treating fibrotic interstitial lung disease (fILD) and lung cancer. The exposure to and distribution in lung tissue of nintedanib is unknown. Hence this study aims to quantify the nintedanib concentrations in normal, fibrotic and borderline-fibrotic lung tissue in fILD patients who underwent a lung transplantation and were treated with nintedanib until transplantation.

Study objective

Higher concentration nintedanib in normal lung tissue compared to fibrotic lung tissue.

Study design

Full analysis of primary and secondary endpoints after last evaluable inclusion. Drug concentrations are measured with LC/MS-MS.

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

Patients treated with nintedanib until lung transplantation

Exclusion criteria

Unwilling to sign informed consent

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-08-2020
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable	
Application type:	Not applicable

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	NL8912
Other	METC Erasmus MC : MEC 19-291

Study results