

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

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON21428

### Source

Nationaal Trial Register

### 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

Erasmus MC  
G.D. Marijn Veerman

0641531792

### Scientific

Erasmus MC  
G.D. Marijn Veerman

0641531792

## 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