

# Phase I study of irinotecan and cisplatin with concurrent thoracic radiotherapy in patients with limited-disease small cell lung cancer

<b>Submission date</b> 11/04/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 11/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/01/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr M J A de Jonge

### Contact details

Erasmus University Medical Centre/Daniel den Hoed Kliniek

Department of Medical Oncology

P.O. Box 5201

Rotterdam

Netherlands

3008 AE

+31 (0)10 439 1760

m.dejonge@erasmusmc.nl

## Additional identifiers

## Study information

### Scientific Title

Phase I study of irinotecan and cisplatin with concurrent thoracic radiotherapy in patients with limited-disease small cell lung cancer

## **Study objectives**

The aim of the study is to determine the Dose-Limiting Toxicity (DLT) and Maximum-Tolerated Dose (MTD) of irinotecan and cisplatin with concurrent thoracic radiotherapy in patients with Limited-Disease Small Cell Lung Cancer (LD-SCLC) at a once every three weeks schedule.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics approval received from the Ethical board of the Erasmus MC on the 18th April 2003 (ref: MEC 216.449/2002/180).

## **Primary study design**

Interventional

## **Study design**

Non-randomised, non-controlled, clinical trial

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Limited-Disease Small Cell Lung Cancer (LD-SCLC)

## **Interventions**

Patients were treated at day one of three-weekly cycles one and four with irinotecan and cisplatin (340 mg and 135 mg, respectively).

A dose-escalation schedule of irinotecan (100, 120, 140, 150 mg) and cisplatin (100 mg) at day one of cycles two and three with concurrent thoracic radiotherapy (total dose 45 Gy) was performed. At each dose level three patients were included.

Dose-Limiting Toxicity (DLT) was defined as one patient in any cohort having any of the following toxicities during cycle two and three (with concurrent thoracic radiotherapy):

1. Grade III/IV non-haematological toxicity despite adequate medication (excluding grade III/IV nausea and vomiting)
2. Grade IV neutropenia lasting for more than five days or complicated by fever and/or platelets less than  $25 \times 10^9/L$ , or
3. Grade IV oesophagitis or grade III oesophagitis lasting for more than two weeks

Maximum Tolerated Dose (MTD) was defined as two or more patients in any cohort experiencing DLT.

## **Intervention Type**

Drug

## **Phase**

Phase I

## **Drug/device/biological/vaccine name(s)**

Irinotecan and cisplatin

**Primary outcome(s)**

The aim of the study is to determine the DLT and MTD of irinotecan and cisplatin with concurrent thoracic radiotherapy in patients with LD-SCLC in a once every three weeks schedule.

**Key secondary outcome(s)**

To determine the efficacy and progression-free and overall survival of irinotecan and cisplatin with concurrent thoracic radiotherapy in patients with LD-SCLC.

**Completion date**

01/01/2006

**Eligibility****Key inclusion criteria**

1. Cytologically or histologically proven SCLC
2. Disease confined to one hemithorax without evidence of cytologically proven malignant pleural effusion
3. No prior chemotherapy and/or radiotherapy
4. Age 18 years or older
5. Performance score zero or one
6. Adequate organ functions:
  - a. White Blood Cells (WBC) greater than  $3.0 \times 10^9/L$
  - b. Absolute Neutrophil Count (ANC) greater than  $1.5 \times 10^9/L$
  - c. platelets greater than  $100 \times 10^9/L$
  - d. serum creatinine less than 135 mmol/L or creatinine clearance according to Cockcroft-Gault formula greater than 60 ml/min
  - e. bilirubin less than 1.25 Upper Limit of Normal (ULN)
  - f. Aspartate Aminotransferase (AST)/Alanine Aminotransferase (ALT) less than 2.5 ULN
  - g. Lactate Dehydrogenase (LDH) less than 1.25 ULN
7. Adequate pulmonary function (Forced Expiratory Volume in one second [FEV1] greater than 30% of predicted, Diffusing capacity of the Lung for Carbon Monoxide [DLCO] greater than 40% of predicted)
8. No prior malignancy unless five years in complete remission except for patients with prior breast cancer or melanoma. Patients with adequately treated basocellular carcinoma of the skin or cervical cancer are eligible
9. Written informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

### **Key exclusion criteria**

1. Other serious illnesses
2. Concurrent therapy with other anti-cancer drugs
3. Pregnancy or lactation
4. Presence of diarrhoea
5. Presence of suspicion of bowel obstruction or chronic inflammatory bowel disease

### **Date of first enrolment**

06/01/2003

### **Date of final enrolment**

01/01/2006

## **Locations**

### **Countries of recruitment**

Netherlands

### **Study participating centre**

**Erasmus University Medical Centre/Daniel den Hoed Kliniek**

Rotterdam

Netherlands

3008 AE

## **Sponsor information**

### **Organisation**

Erasmus Medical Centre (The Netherlands)

### **ROR**

<https://ror.org/018906e22>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Aventis Pharma (The Netherlands)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2008	04/01/2021	Yes	No