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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
11/04/2007		[_] Protocol		
<b>Registration date</b> 11/04/2007	<b>Overall study status</b> Completed	[] Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
05/01/2021	Cancer			

### 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**

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## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## 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 Call 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).

**Study design** Non-randomised, non-controlled, clinical trial

**Primary study design** Interventional

**Secondary study design** Non randomised controlled trial

**Study setting(s)** Not specified

**Study type(s)** Treatment

#### Participant information sheet

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 x 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 measure

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.

#### Secondary outcome measures

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

#### Overall study start date

06/01/2003

#### **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 x 10^9/L
- b. Absolute Neutrophil Count (ANC) greater than 1.5 x 10^9/L
- c. platelets greater than 100 x 10^9/L

d. serum creatinine less than 135 mmol/L or creatinine clearance according to Cockroft-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

#### Age group

Adult

#### **Lower age limit** 18 Years

**Sex** Not Specified

Target number of participants

9

#### 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)

#### Sponsor details

Daniel den Hoed Kliniek Afdeling Interne Oncologie P.O. Box 5201 Rotterdam Netherlands 3008 AE

**Sponsor type** Hospital/treatment centre

Website http://www.erasmusmc.nl/

ROR https://ror.org/018906e22

## Funder(s)

Funder type Industry

**Funder Name** Aventis Pharma (The Netherlands)

## **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

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?
<u>Results article</u>	results	01/07/2008	04/01/2021	Yes	No