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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

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 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(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 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

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