Phase 1 study of irinotecan and cisplatin with concurrent thoracic radiotherapy in patients with limited-disease small cell lung cancer (LD-SCLC).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23572

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Limited-disease small cell lung cancer (LD-SCLC).

Sponsors and support

Primary sponsor: Department of Medical Oncology
Erasmus University Medical Center / Daniel den Hoed Kliniek
3008 AE ROTTERDAM
Source(s) of monetary or material Support: Aventis Pharma B.V., the Netherlands.

Intervention

Outcome measures

Primary outcome

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 LD-SCLC ias a onve every three weeks schedule.

Secondary outcome

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

Study description

Background summary

Chemotherapy with concurrent thoracic radiotherapy (TRT) is considered standard treatment for limited-disease small cell lung cancer (LD-SCLC).

The introduction of new chemotherapeutic agents and radiotherapy regimens may improve the prognosis of patients with LD-SCLC.

The camptothecin derivative irinotecan has shown good results in the treatment of patients with ED-SCLC.

Cisplatin and irinotecan have synergistic anti-tumor effects.

The present phase I trial was designed to determine the feasibility and tolerability of irinotecan and cisplatin in a 3-weekly schedule with concurrent once-daily TRT in LD-SCLC.

Study objective

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 LD-SCLC as a once every three weeks schedule.

Study design

N/A

Intervention

Patients were treated at day 1 of three-weekly cycles 1 and 4 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

1 of cycles 2 and 3 with concurrent thoracic radiotherapy (total dose 45 Gy) was performed. At each dose level 3 patients were included.

Dose-limiting toxicity (DLT) was defined as one patient in any cohort having any of the following toxicities during cycle 2 and 3 (with concurrent thoracic radiotherapy), grade III/IV non-haematological toxicity despite adequate medication (excluding grade III/IV nausea and vomiting), grade IV neutropenia lasting for more than five days or complicated by fever and/or platelets < 25 x 10^9/L, or 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.

Contacts

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Eligibility criteria

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 0 or 1;

6. Adequate organ functions (WBC > 3.0 x 10^9/L, ANC > 1.5 x 10^9/L, platelets > 100 x 10^9/L, serum creatinine < 135 mmol/L or creatinine clearance according to Cockroft-Gault formula > 60 ml/min, bilirubin < 1.25 ULN, AST/ALT < 2.5 ULN and LDH < 1.25 ULN);

7. Adequate pulmonary function (FEV1 > 30% of predicted, DLCO > 40% of predicted);

8. No prior malignancy unless 5 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.

Exclusion criteria

1. Other serious ilnesses;

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	06-01-2003
Enrollment:	9
Type:	Actual

Ethics review

Positive opinion Date:	20-03-2007
Application type:	First submission

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	NL913
NTR-old	NTR937
Other	:
ISRCTN	ISRCTN75771514

Study results

Summary results
Lung Cancer. 2008 Jul;61(1):123-8. Epub 2008 Jan 7.