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

Gepubliceerd: 20-03-2007 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23572

Bron
NTR

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: Department of Medical Oncology
Erasmus University Medical Center / Daniel den Hoed Kliniek
3008 AE ROTTERDAM
Overige ondersteuning: Aventis Pharma B.V., the Netherlands.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	06-01-2003
Aantal proefpersonen:	9
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-03-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL913
NTR-old	NTR937
Ander register	:
ISRCTN	ISRCTN75771514

Resultaten

Samenvatting resultaten

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