A phase II study of docetaxel/carboplatin as secondline treatment in patients with refractory or relapsed SCLC

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To evaluate the anti-tumor activity of a docetaxel/carboplatin regimen in patients with refractory or relapsed SCLC. Furthermore to asses the safety profile of the docetaxel/carboplatin combination.In patients who have experienced FN, the efficacy...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON33924

Source
ToetsingOnline

Brief title
2nd line Docetaxel/Carboplatin in patients with SCLC-ED.

Condition

- Bronchial disorders (excl neoplasms)

Synonym
refractory small cell lungcancer; SCLC-ED

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: gedeeltelijke financiering door de sponsor,Sanofi-aventis

Intervention

Keyword: 2nd line, Docetaxel/Carboplatin, refractory SCLC

Outcome measures

Primary outcome

Primary endpoint: response rate

Secondary outcome

Secondary endpoint(s): time to progression, response duration, safety profile and survival. Recurrence of FN after start of Neulasta or levofloxacin. The difference in cumulative dose and dose intensity in patients without FN (and thus without prophylaxis), in patients receiving secondary prophylaxis with pegfilgrastim and/or patients receiving secondary prophylaxis with levofloxacin.

Study description

Background summary

Small cell lung cancer (SCLC) is diagnosed in approximately 15 % of all the lung cancer cases. SCLC is recognized by its rapid tumor growth, with a high chemo- and radio sensitivity, and by its high metastasizing potential. Patients with extensive-stage disease have a 5-year survival rate of 1% to 2%.
Almost 2/3 of the patients have already extensive disease (ED) upon diagnosis.The recommended treatment of ED-SCLC is systemic chemotherapy, considered to be the standard first line treatment option in all patients with SCLC regardless of performance status and age. World-wide, the most commonly used regimen for 1st line treatment is the combination of cisplatin-etoposide, while in the Netherlands the cyclophosphamide, doxorubicin and etoposide regimen is widely used.Survival outcome with these regimens appear similar. Unfortunately, relapses occur in all patients and responses to second-line chemotherapy have proven to be of
short term. Until recently, there were no registered drugs for treatment of relapsing SCLC. Phase II studies with docetaxel in first line - and second line treatment of SCLC demonstrated that docetaxel is an active agent in these

patient groups. Therefore docetaxel seems suitable for evaluation in combination with other cytotoxic drugs active in this disease. Until now no studies have been performed with a combination of docetaxel and platinum in this group of previously treated SCLC patients.
A phase II study in previously untreated patients with SCLC shows that the combination docetaxel and cisplatin/carboplatin is an active and well tolerated regimen in extensive SCLC.
Based on the experience in other pre-treated patient populations (for example ovarian cancer patients) the combination of docetaxel and carboplatin is associated with neutropenia in up to 60% of patients. In addition,
lung cancer patients are at risk of developing febrile neutropenia (FN). Based on prior results by Lalami et al
the proportion of patients with recurrent FN after secondary prophylaxis with G-CSF (for example pegfilgrastim) is expected to be close to 0%. Recently, in solid tumor patients receiving standard dose chemotherapy,
levofloxacin proved to be an effective and convenient primary prophylactic strategy. However, the efficacy of levofloxacin as secondary prophylactic strategy is not known.

Study objective

To evaluate the anti-tumor activity of a docetaxel/carboplatin regimen in patients with refractory or relapsed SCLC. Furthermore to asses the safety profile of the docetaxel/carboplatin combination.
In patients who have experienced FN, the efficacy of pegfilgrastim and levofloxacin with regard to secondary prophylaxis will be compared.

Study design

This study will be a open label non-randomized study conducted in patients with refractory or relapsed SCLC.
It is a phase II study with 50 patients.
Docetaxel infusion 75 mg/m2 , carboplatin AUC = 6 mg/ml•min day 1, every 21 days for 4-6 cycles.
Patients experiencing FN will be randomized (1:1) to receive prophylaxis with pegfilgrastim (Neulasta®) 6 mg once per cycle on day 2 or levofloxacin 500 mg orally OD for 7 days (day 2-8) during the following cycles.

Intervention

Docetaxel infusion 75 mg/m2 , carboplatin AUC = 6 mg/ml•min day 1, every 21 days for 4-6 cycles

Study burden and risks

Hospital visits and tests are not different from the standard treatment. Stress

due to adverse events is not
essential higher estimated. Special risks are not expected. Frequently medical examination and control of laboratory results will be done. Detailed instruction will be given about what do to in case of serious toxicity.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Histologically proven SCLC at the first diagnosis.
Refractory or relapsed SCLC
Measurable disease according to RECIST criteria
Patients must have fully recovered from toxic effects of previous antitumour therapy.
Age > 18 years.
WHO performance status 0,1 or 2 (Appendix II).

Exclusion criteria

More than one line of chemotherapy for metastatic disease
Pregnant or lactating women or women of childbearing potential not adhering to adequate anti conceptive measures
History of other invasive malignancy within the last 5 years (other than non melanoma skin cancer or excised cervical carcinoma in situ).
Clinical evidence CNS metastasis.
Symptomatic peripheral neuropathy > grade 2 according (NCI CTC, Appendix III)
Definite contraindications for the use of corticosteroids

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2007
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Carboplatin
Generic name:	Carboplatin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Taxotere

Generic name:	Docetaxel
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	27-02-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-06-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-09-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-10-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-01-2008
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-09-2008
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-10-2008

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-05-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
EudraCT	EUCTR2006-004847-47-NL
CCMO	NL16406.100.07