A phase 1 study with cisplatin and pemetrexed administered before or after stereotactic radiotherapy (SRT) in patients with stage IB non-small-cell lung cancer (NSCLC).

Gepubliceerd: 19-05-2009 Laatst bijgewerkt: 18-08-2022

Establish the safety and feasibility of sequential chemotherapy and SRT.

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

Samenvatting

ID

NL-OMON23245

Bron
Nationaal Trial Register

Verkorte titel
Cisplatin-pemetrexed and SRT in stage IB NSCLC

Aandoening

non-small-cell lung cancer. longkanker

Ondersteuning

Primaire sponsor: prof. dr. EF Smit
Overige ondersteuning: Eli Lilly

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Safety and feasibility of sequential chemotherapy and SRT.

Toelichting onderzoek

Achtergrond van het onderzoek

Phase I study on safety and feasibility of cisplatin-pemetrexed administered before or after SRT in stage IB NSCLC. A total of 20 patients with inoperable stage IB NSCLC, or patients with stage IB NSCLC refusing surgery, who would receive SRT monotherapy as standard treatment outside the study, will be included.

Doel van het onderzoek

Establish the safety and feasibility of sequential chemotherapy and SRT.

Onderzoeksopzet

Patients participating in this study will be administered intravenously 3 courses (1 course = 3 weeks) of cisplatin/pemetrexed, before or after SRT. Hospitalization length is 3 days for 1 course. After the treatment, checkups are weekly for the first 4 weeks, then at 3 months, 6 months, 1 year to 5 year.

Onderzoeksproduct en/of interventie

In the first 10 patients, 3 cycles of cisplatin-pemetrexed will be administered after SRT; In the second arm, 3 identical cycles of chemotherapy will be administered preceding SRT treatment.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Any histologically or cytologically proven NSCLC;

2. Stage IB NSCLC (T2N0M0);

3. FDG-PET scan consistent with stage IB NSCLC;

4. Age 18 years or older;

5. Patients should be fit to undergo chemotherapy and be eligible for SRT using 5 or 8 fractions as specified;

6. Adequate organ function;

7. Signed informed consent;

8. Male and female patients with reproductive potential must use an approved contraceptive method, if appropriate. Female patients with childbearing potential must have a negative serum pregnancy test within 7 days prior to study enrollment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnant or lactating women;

2. Concomitant treatment with any other experimental drug under investigation;

3. Inability or unwillingness to take folic acid or vitamin B-12 supplementation;

4. Diagnosis of a synchronous second malignancy;

5. Small-Cell Lung cancer (SCLC) or a mixed SCLC-NSCLC;

6. Prior thoracic radiotherapy;

7. Prior systemic anti-cancer chemotherapy.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-05-2009
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	NL1714
NTR-old	NTR1824
Ander register	2008-004731-37 : 2008/251
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A