Phase II Study of cisplatin and everolimus in patients with metastatic or unresectable neuroendocrine carcinomas (NEC) of extrapulmonary origin

Gepubliceerd: 16-01-2015 Laatst bijgewerkt: 19-03-2025

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24870

Bron
Nationaal Trial Register

Verkorte titel
NEC

Aandoening

patients with metastatic or unresectable neuroendocrine carcinomas (NEC) of extrapulmonary origin

Ondersteuning

Primaire sponsor: NKI-AVL
Overige ondersteuning: fund=initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint of this study will be Disease Control Rate (DCR), defined as the sum of Overall Response Rate (ORR) consisting of Complete (CR), Partial Response Rate (PR) and stable disease (SD), all according to RECIST 1.1

Toelichting onderzoek

Onderzoeksopzet

Response to treatment will be assessed every 9 weeks and patients with stable disease or a better response will be allowed to continue protocol treatment up to 6 cycles . After this (combined) treatment, patients will be allowed to continue with single-agent everolimus until disease progression or unacceptable toxicity. All patients will be followed for toxicity, tumour progression and survival

Onderzoeksproduct en/of interventie

everolimus and cisplatin

Contactpersonen

Publiek

[default]
The Netherlands

Wetenschappelijk

[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Pathologically confirmed unresectable locally advanced NEC where no curative

(chemoradiation) treatment options are available, and/or metastatic NECs of extrapulmonary origin as first line therapy NEC of extrapulmonary origin (WHO 2010 classification; Ki67 >20 %) including merkel cell carcinoma.

2. Measurable disease according to RECIST 1.1, on CT-scan or MRI

3. ECOG Performance status 0-2 (see Appendix 2)

4. Adequate bone marrow function as shown by: ANC¡Ý1.5 x 109/L, Platelets ¡Ý100 x 109/L, Hb >6 mmol/L

5. Adequate liver function as shown by:

Total serum bilirubin ¡Ü1.5 ULN

ALT and AST ¡Ü2.5x ULN (¡Ü5x ULN in patients with liver metastases)

6. Adequate renal function: calculated creatinin clearance > 60ml/min. (Cockcroft-Gault formula)

7. Life expectancy of at least 3 months.

8. Male or female age ¡Ý 18 years.

9. Signed informed consent.

10. Able to swallow and retain oral medication.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous chemotherapy for metastatic or unresectable NEC of extrapulmonary origin. (prior peri-operative chemotherapy or chemoradiation for curative intention is allowed if at least 6 months have elapsed between completion of this therapy and enrolment into the study).

2. Prior therapy with mTOR inhibitors (e.g. sirolimus, temsirolimus, deforolimus, everolimus)

3. Other malignancy within the last 5 years, except for carcinoma in situ of the cervix, or basal cell carcinoma.

4. Known intolerance or hypersensitivity to everolimus or other rapamycin analogs (e.g. sirolimus, temsirolimus) or cisplatin

5. Known impairment of gastrointestinal (GI) function or GI disease that may significantly alter the absorption of oral everolimus

6. Uncontrolled diabetes mellitus as defined by HbA1c >8% despite adequate therapy. Patients with a known history of impaired fasting glucose or diabetes mellitus (DM) may be included, however blood glucose and antidiabetic treatment must be monitored closely throughout the trial and adjusted as necessary

7. Patients who have any severe and/or uncontrolled medical conditions such as: a. unstable angina pectoris, symptomatic congestive heart failure, myocardial infarction ¡Ü6 months prior to randomization, serious uncontrolled cardiac arrhythmia. b. active or uncontrolled severe infection, c. liver disease such as cirrhosis, decompensated liver disease, and known history chronic hepatitis d. known severely impaired lung function (spirometry and DLCO 50% or less of normal and O2 saturation 88% or less at rest on room air), e. active, bleeding diathesis;

8. Chronic treatment with corticosteroids or other immunosuppressive agents

9. Known history of HIV seropositivity

10. Pregnant or nursing (lactating) women

11. Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception during dosing and for 8 weeks after stopping study treatment.

12. Sexually active males, unless they use a condom during intercourse while taking study medication and for 8 weeks after stopping study medication.

13. History of documented congestive heart failure; angina pectoris requiring medication; evidence of transmural myocardial infarction on ECG; poorly controlled hypertension (systolic BP >180 mmHg or diastolic BP >100 mmHg); clinically significant valvular heart disease; or high risk uncontrollable arrhythmias.

14. Patients with dyspnoea at rest due to complications of advanced malignancy or other disease, or who require supportive oxygen therapy.

15. History or clinical evidence of brain metastases.

16. Any investigational drug treatment within 4 weeks of start of study treatment.

17. Radiotherapy within 4 weeks of start of study treatment (2 week interval allowed if palliative radiotherapy given to bone metastastic site peripherally and patient recovered from any acute toxicity).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-04-2015
Aantal proefpersonen:	39
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47011
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4939
NTR-old	NTR5041
CCMO	NL50842.031.15

Register	ID
OMON	NL-OMON47011

Resultaten