Onderhoudsbehandeling met gemcitabine bij patiënten met longvlieskanker bij wie de tumor niet groeit na de eerste lijn chemotherapie met een pemetrexed –platinum combinatie. Een gerandomiseerde fase II studie.

Gepubliceerd: 20-08-2013 Laatst bijgewerkt: 15-05-2024

Determine the potential improvement of the duration of progression-free survival by maintenance treatment with gemcitabine.

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

Samenvatting

ID

NL-OMON26963

Bron
Nationaal Trial Register

Verkorte titel
NVALT19

Aandoening

Malignant pleural mesothelioma
Borstvlieskanker

Ondersteuning

Primaire sponsor: Stichting NVALT studies
Overige ondersteuning: KWF, Stichting NVALT studies and Stichting Mesotheliomen

Werkgroep Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Progression free survival, defined as time from randomisation to disease progression or death (in case no progression has been documented)

Toelichting onderzoek

Achtergrond van het onderzoek

Summary
Study title: Switch maintenance treatment with gemcitabine for patients with malignant mesothelioma who do not progress after 1st line therapy with a pemetrexed-platinum combination. A randomised open label phase II study. NVALT19

Principal Research Center: Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital

Methodology: Randomized phase II trial

Scientific rationale: The aim of this study is to perform a randomised phase II clinical trial to characterise the potential clinical benefit, toxicity, and biomarkers of outcome for maintenance therapy with gemcitabine in patients with malignant pleural mesothelioma who have completed first line chemotherapy without progression. Evidence from both mesothelioma studies and other solid malignancies indicates the potential to deliver real benefits to patients using a maintenance strategy. The choice of gemcitabine builds on previous work in mesothelioma and non-small cell lung cancer, which proposes a non-cross resistant ‘switch maintenance’ agent.

Objectives

Primary objective:

Determine the potential improvement of maintenance treatment with gemcitabine on the duration of progression-free survival.

Secondary objective:

• To compare the objective radiological response (ORR) rate

• To compare overall survival (OS)

• To assess and compare the lung function

• To describe the toxicity

• To identify potential biomarkers

Exploratory objectives:

• To correlate tumour biomarkers and SNP’s with PFS and severe toxicity

• Explore new techniques to analyse standard imaging data

Primary endpoint: The primary endpoint is progression free survival, defined as time from randomisation to disease progression or death (in case no progression has been documented)

Eligibility Criteria

Inclusion criteria

• Patients with histologically or cytologically proven malignant mesothelioma

• Age >18 years.

• At the date of randomisation, the patients must have completed 4 cycles of first-line chemotherapy with a platinum (cisplatin or carboplatin) and pemetrexed combination at least 21 days but no more than 42 days prior to study entry, and have no evidence of progressive disease following first-line treatment.

• Measurable or evaluable disease, according to modified RECIST.

• Ability to understand the study and give signed informed consent prior to beginning of protocol specific procedures.

• WHO performance status ≤ 2

• Adequate organ function as evidenced by the following peripheral blood counts or serum chemistries at study entry:

o Hematology: Neutrophil count ≥ 1.5 x 109/l, Platelets ≥ 100 x 109/l, Hemoglobin ≥ 6.2 mmol/l.

o Hepatic function as defined by serum bilirubin ≤ 1.25 times the upper limit of normal (ULN), ALT and AST ≤ 2.5 times the ULN, except if liver metastases then ALAT and ASAT < 5 times the ULN.

o Renal function as defined by serum creatinine ≤ 1.25 times ULN or creatinine clearance ≥ 50 ml/min (by Cockcroft-Gault formula).

Exclusion criteria

• Active uncontrolled infection or severe cardiac dysfunction (such as New York Heart Association Class III or IV cardiac disease, myocardial infarction within the last 6 months, unstable arrhythmias, or unstable angina).

• Presence of symptomatic CNS metastases.

• Radiotherapy within 2 weeks prior to study entry.

• Unstable peptic ulcer, unstable diabetes mellitus or other serious disabling condition.

• Concomitant administration of any other experimental drugs under investigation.

Number of patients: 124 patients will be randomized

Study treatment

Arm A: Gemcitabine will be given intravenously at day 1 and day 8 of a 3-weeks cycle at a dose of 1250 mg/m2

Arm B: Best supportive care

Treatment duration: Treatment continues until disease progression, severe toxicity, serious intercurrent illness, patient request for discontinuation, need or use for any other anti-cancer agent other than protocol treatment, except for palliative radiotherapy.

Doel van het onderzoek

Determine the potential improvement of the duration of progression-free survival by maintenance treatment with gemcitabine.

Onderzoeksopzet

Every 6 weeks until off-study, thereafter every 12 weeks until dead

Onderzoeksproduct en/of interventie

- Maintenance Gemcitabine will be given intravenously at day 1 and day 8 of a 3-weeks cycle at a dose of 1250 mg/m2

- Best Supportive Care

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients with histologically or cytologically proven malignant mesothelioma

• Age >18 years.

• At the date of randomisation, the patients must have completed 4 cycles of first-line chemotherapy with a platinum (cisplatin or carboplatin) and pemetrexed combination at least 21 days but no more than 42 days prior to study entry, and have no evidence of progressive disease following first-line treatment.

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o Renal function as defined by serum creatinine ≤ 1.25 times ULN or creatinine clearance ≥ 50 ml/min (by Cockcroft-Gault formula).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Active uncontrolled infection or severe cardiac dysfunction (such as New York Heart Association Class III or IV cardiac disease, myocardial infarction within the last 6 months, unstable arrhythmias, or unstable angina).

• Presence of symptomatic CNS metastases.

• Radiotherapy within 2 weeks prior to study entry.

• Unstable peptic ulcer, unstable diabetes mellitus or other serious disabling condition.

• Concomitant administration of any other experimental drugs under investigation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2013

Aantal proefpersonen:	124
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	20-08-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47831
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3847
NTR-old	NTR4132
CCMO	NL43041.031.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON47831

Resultaten

Samenvatting resultaten
N/A