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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26963

Source
Nationaal Trial Register

Brief title
NVALT19

Health condition

Malignant pleural mesothelioma
Borstvlieskanker

Sponsors and support

Primary sponsor: Stichting NVALT studies
Source(s) of monetary or material Support: KWF, Stichting NVALT studies and Stichting Mesotheliomen Werkgroep Nederland

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Adverse events

- Objective radiological response rate in patients with measurable disease

- Overall survival

- Changes in vital capacity and FEV1.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

- 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

Contacts

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

• Concomitant administration of any other experimental drugs under investigation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2013
Enrollment:	124
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-08-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47831
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A