Biomarkers for improving the (cost-)effectiveness and safety of pemetrexed

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON39476

Source
ToetsingOnline

Brief title
biomarkers and pemetrexed

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer, non small cell lung carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Zonmw

Intervention

Keyword: biomarkers, mesothelioma, non-small cell lung cancer, pemetrexed

Outcome measures

Primary outcome

This is an observational study. The primairy outcome is the question whether

there is a relation between pharmacogenetics and pharmacokinetics and repons to

treatment with pemetrexed

Secondary outcome

relation between pharmacogenetics and pharmacokinetics and quality of life

Study description

Background summary

In Holland over 10.000 patients are diagnosed with lungcancer anually. A major part of these patients will be treated with chemotherapy during the course of their disease. Malignant pleural mesothelioma is a rare thoracic malignancy, which is diagnosed in approximately 500 patients in Holland annually. The treatment of this disease also often consists of chemotherapy. One of the newest most effective chemotherapeutic agents used for the treatment of these malignancies is pemetrexed. It is a very expensive chemotherapeutic agent. It is known that some patients do respond better then others. It is however possible to identify patients who respond well. At present this can only be established during treatment of patients, when responses are assessed. In case of a non-reponsiveness of the tumor patients haven been treated unnecessarily and other possible effective treatments are started later or not.

We have performed studies on the responsiveness of tumorcells to pemetrexed (Hou et al, J Thor Oncol 2012). Also we already studied the possibility to measure blood and intracellular levels of agents (Meesters et al 2011).

Een zeldzamere thoracale maligniteit is het pleurale maligne mesothelioom, waarmee ongeveer 500 mensen per jaar gediagnosticeerd worden. Ook bij deze maligniteit wordt een groot deel van de patiënten behandeld met chemotherapie.

Study objective

The objective of this study proposal is to investigate whether use of biomarkers (intracellular pemetrexed levels and/or genetic loci) for response and toxicity to pemetrexed improves the effectiveness of therapy and cost-effectiveness ratio. This objective consists of the following research questions:
1. What is the association between predefined candidate pharmacogenetic determinants and tumor response, time to progression, toxicity, and survival in those on pemetrexed.
2. What is the association between cellular pharmacokinetics and tumor response, time to progression, toxicity, and survival in those on pemetrexed.
3. What is the improvement in overall effectiveness and cost-effectiveness if non-responders and those vulnerable to toxicity are not treated with pemetrexed.
4. What is the relation between predetermined immunohistochemic stainings on available tumortissue and tumor response, time to progression, toxicity, and survival in those on pemetrexed.

Study design

We will perform a prospective cohort study in the first 200 patients who started treatment with pemetrexed, and gave written informed consent to participate in the study. They will be followed from first treatment with pemetrexed until the first occurrence of one of the following events: death, discontinuation of pharmacotherapy with pemetrexed, toxicity or the end of the study period of two years of follow-up.

Study burden and risks

The decision to start a treatment with pemetrexed is taken by the treating physician. If a patient is willing to participate in the trial they will be asked to cede extra blood during a regular bloodsample. This gives no extra risks. Also patients are asked to fill quality of life questionairs. This will take time for a patient and can give extra discomfort as for patients with cancer it can be extra burdensome to answer questions regarding quality of life

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

patients with non-small cell, non-squamous lungcarcinoma or malignant pleural mesothelioma who have an indication for treatment with pemetrexed containing chemotherapy, both in first line treatment as in following treatment lines and as maintenance therapy.

Exclusion criteria

non able to read dutch
clinical condition not fit to receive pemetrexed chemotherapy

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-10-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	30-08-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-07-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL39230.078.12