Monitoring the microcirculation of patients with advanced lungcancer treated with bevacizumab and chemotherapy using optical spectroscopy.

Published: 26-07-2007
Last updated: 20-05-2024

2.1 Primary objectives Primary objective is scientific research to study the additional effect of bevacizumab on hypoxia related parameters. 2.2 Secondary objectives a) To compare the efficacy of bevacizumab with pre-treatment obtained values of...

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

Summary

ID

NL-OMON30524

Source
ToetsingOnline

Brief title
DPS, Lungcancer

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lungcancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: advanced lungcancer, bevacizumab, Spectroscopy

Outcome measures

Primary outcome

oxygen saturation and vesseldiameter in the tumour before and after

chemotherapy with or without bevacizumab

Secondary outcome

survival of the patients

Study description

Background summary

Lungcancer is the second most common cancer in men and women, and is the leading cause of cancer related death. In industrialized countries it kills more patients than breast, colorectal and prostate cancer combined. Eighty-five percent of patients with lungcancer have non-small-cel-lungcancer (NSCLC), and 60% of these patients present with an incurable stage IIIB or IV disease. Prognosis of advanced lungcancer (both small cell and non-small cell) is bad. Unfortunately, only palliative rather than curative treatment options are present for these advanced cancers. Platinum-based chemotherapy is currently the standard treatment in these patients and median survival time is typically 6-9 month after this standard therapy. [1]

Study objective

2.1 Primary objectives

Primary objective is scientific research to study the additional effect of bevacizumab on hypoxia related parameters.

2.2 Secondary objectives

a) To compare the efficacy of bevacizumab with pre-treatment obtained values of blood hypoxia related parameters.
b) To study the effect of standard treatment of chemotherapy without bevacizumab on hypoxia related parameters.

Study design

suspicion of lung carcinoma
*
bronchoscopy with DPS after informed consent METC
*
NSCLC stage IV disease or extended SCLC
*
informed consent present trial randomisation
* *
standard treatment with bevacizumab standard treatment without

bevacizumab

* *
repeated bronchoscopy with DPS
*
treatment according to institutional policy

Study burden and risks

Standard risk by bronchscopy: damaging of the vocalcord, haemoptoe, pneumothorax, hypoxemia, arrhythmias.

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

· suspected endoscopically visible tumour
· written informed consent
· histologycally or cytologicoly documented inoperable advanged stage IV NSCLC or extensive SCLC
· WHO 1-2
· Life expectancy > 12weeks
· Adequate hemologycal/liver/renal function
· INR< 1,5
· In case of female, not pregnant or breastfeeding

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	26-07-2007
Application type:	First submission

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	NL13188.078.06