Observational study;
Pilot study assessing sildenafil effect on lung tumour blood flow.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON19896

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Non-small cell lung cancer.

Sponsors and support

Primary sponsor: Prof. Dr. E.F. Smit
ef.smit@vumc.nl
Source(s) of monetary or material Support: Fund=initiator=sponsor.

Intervention

Outcome measures

Primary outcome

Tumour perfusion change after sildenafil.

Secondary outcome

N/A

Study description

Background summary

The aim of this pilot study is to assess if sildenafil induced pulmonary vasodilatation leads to an associated increase in tumour blood flow in NSCLC. If this appears to be the case then a larger scale study would be performed to confirm this as sildenafil might then potentially augment the efficacy of chemotherapy or act as a radiosensitising agent in the treatment of NSCLC.

A baseline dynamic CT perfusion scan will be performed to assess baseline tumour perfusion. On the treatment day patients will receive 50 mg sildenafil orally (time point 0). One hour after administration a CT perfusion will be performed to assess tumour perfusion post sildenafil. By comparing the baseline and post-treatment scans the effect on tumour perfusion will be estimated. Blood pressure and pulse will be monitored at 0, 15, 30, 45, 60 and 120 mins to assess for possible systemic hypotension.

Study objective

Does sildenafil improve tumour perfusion?

Study design

Baseline and 1 hour post sildenafil.

Intervention

1. Baseline CT perfusion scan;

2. 50 mg sildenafil;

3. 1 hour later: CT perfusion scan.

In addition to CT perfusion scans we will perform H2O PET scans to assess tumor perfusion. The PET scans will be performed at baseline and 60 minutes after sildenafil administration (Ie. Same time points as CT scans). The primary outcome of change in tumor perfusion will be

assessed by the CT scans and PET scans.

Contacts

Public
VU university medical centre
Department of pulmonary diseases
PO Box 7057

Joline Lind
Amsterdam 1007 MB
The Netherlands
Scientific
VU university medical centre
Department of pulmonary diseases
PO Box 7057

Joline Lind
Amsterdam 1007 MB
The Netherlands

Eligibility criteria

Inclusion criteria

1. Age > 18 years;

2. WHO performance status 0-1;

3. Adequate hematological, renal and hepatic functions:

a. total bilirubin < 1.5 x UNL;

b. ASAT/ALAT < 2 x UNL;

c. alkaline phosphatase < 5 x UNL;

d. creatinine < 130 mmol/L;

4. Primary tumour size ¡Ý1cm;

5. Written informed consent.

Exclusion criteria

1. Concurrent NTG, ritonivir, azoles, other P450 inhibitors;

2. Concurrent anti-hypertensive or nitrate medications;

3. Hypersensitivity to sildenafil/component of formulation;

4. Contrast allergy;

5. Hypotension <90/50mmg;

6. Other serious diseases such as heart failure, unstable angina, MI/CVA/serious arrhythmia within 6 months, diabetes;

7. History of visual loss and genetic degenerative retinal disease e.g. retinitis pigmentosa;

8. Pregnancy/lactation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2007
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-11-2007
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
NTR-new	NL1088
NTR-old	NTR1121
Other	MEC nr : 07/237.
ISRCTN	Geen aanvraag/Observational study

Study results

Summary results
N/A