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

Gepubliceerd: 06-11-2007 Laatst bijgewerkt: 13-12-2022

Does sildenafil improve tumour perfusion?

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON19896

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Non-small cell lung cancer.

Ondersteuning

Primaire sponsor: Prof. Dr. E.F. Smit
ef.smit@vumc.nl
Overige ondersteuning: Fund=initiator=sponsor.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Tumour perfusion change after sildenafil.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Does sildenafil improve tumour perfusion?

Onderzoeksopzet

Baseline and 1 hour post sildenafil.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

VU university medical centre
Department of pulmonary diseases
PO Box 7057

Joline Lind
Amsterdam 1007 MB
The Netherlands

Wetenschappelijk

VU university medical centre
Department of pulmonary diseases
PO Box 7057

Joline Lind
Amsterdam 1007 MB
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2007
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-11-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1088
NTR-old	NTR1121
Ander register	MEC nr : 07/237.
ISRCTN	Geen aanvraag/Observational study

Resultaten

Samenvatting resultaten
N/A