Effect Of CO2 On Nebulized Tobramycin.

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1. Evaluation of pulmonary deposition of inhaled Tobramycin with 99mTc-DTPA tracer is feasible using SPECT-CT scans; 2a. Pulmonary deposition of Tobramycin improves with concomitant inhalation of carbon dioxide enriched ambient air; 2b. Pulmonary...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25652

Bron
NTR

Aandoening

Bronchiectasis

Ondersteuning

Primaire sponsor: VU University medical center
Overige ondersteuning: VU University medical center (department of pulmonology)

TEVA Pharma NL

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Phase A study:
Feasibility study (SPECT/CT). Mean clearance rate (and range) of 99mTc-DTPA.

Phase B study:
1. Total and peripheral deposition of inhaled tobramycin (with and without carbon dioxide

and with two different nebulizers);
2. Pharmacokinetics: C max (peak concentration), AUC (0-8 hours), T max (time to reach maximum concentration), T1/2 (half life).

Toelichting onderzoek

Achtergrond van het onderzoek

Pseudomonas aeruginosa colonization is an independent predictor of mortality in bronchiectasis patients. Non-CF bronchiectasis patients often experience symptom relief and improvement in lung function, however studies have failed to show significant improvement. Enhancing deposition of inhaled antibiotics and lung recruitment may improve the response to inhaled antibiotic treatment. Inhaling a low concentration of carbon dioxide (CO2) during antibiotic nebulization alters respiratory parameters. By changing these parameters one can try to alter the peripheral deposition of inhaled medication, which may improve treatment. SPECT/CT is the preferred technique to obtain information on deposition of inhaled drugs. However it is unknown if these measurements are feasible with inhalation of technetium DTPA (99mTc-DTPA) and tobramycin, due to the requirement of a relatively steady state uptake. This randomised cross-over proof of principle study investigates the feasibility of SPECT-CT scans in the evaluation of pulmonary deposition of Tobramycin. In addition, concomitant inhalation of CO2 enriched ambient air and the use of the breath-actuated mode of the AeroEclipse II nebulizer with adjusted Tobramycin dose are evaluated.

Doel van het onderzoek

1. Evaluation of pulmonary deposition of inhaled Tobramycin with 99mTc-DTPA tracer is feasible using SPECT-CT scans;

2a. Pulmonary deposition of Tobramycin improves with concomitant inhalation of carbon dioxide enriched ambient air;

2b. Pulmonary deposition of Tobramycin with the breath-actuated mode of the AeroEclipse II nebulizer and adjusted dose is equal to deposition with the Pari LC plus nebulizer.

Onderzoeksopzet

Analysis at end of study.

Onderzoeksproduct en/of interventie

1. Nebulization of 99mTc-DTPA and tobramycin 125 mg without carbon dioxide enriched air with an Aero Eclipse II ® nebulizer;

2. Nebulization of 99mTc-DTPA and tobramycin 125 mg with carbon dioxide enriched ambient

air with an Aero Eclipse II ® nebulizer;

3. Nebulization of 99mTc-DTPA and tobramycin 300 mg without carbon dioxide enriched air with a Pari LC Plus ® nebulizer.

The interventions have a duration of 3 days with at least 72 hours in between and a maximum pause of 1 week.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Bronchiectasis;

2. Antibiotic inhalation therapy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age <21 years;

2. Chronic respiratory insufficiency defined according to the GOLD criteria (PaO2 < 60 mmHg or PaCO2 > 50 mmHg, WHO Global Initiative for Chronic Obstructive Lung Disease 2006);

3. Renal insufficiency defined as renal creatinine clearance of < 30 ml/minute;

4. Neuromuscular diseases;

5. Impaired hearing;

6. Pregnant or breastfeeding;

7. Bronchiectasis exacerbation during last 4 weeks;

8. History of panic attacks.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2012
Aantal proefpersonen:	14
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-04-2012
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	NL3255
NTR-old	NTR3407
Ander register	CWO : Pro12/15

Resultaten

Samenvatting resultaten
N/A