Effect Of CO2 On Nebulized Tobramycin.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25652

Source
Nationaal Trial Register

Health condition

Bronchiectasis

Sponsors and support

Primary sponsor: VU University medical center
Source(s) of monetary or material Support: VU University medical center (department of pulmonology)

TEVA Pharma NL

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

1. Peak expiratory flow;

2. Respiratory parameters;

3. Borg score (subjective sensation of dyspnoea).

Study description

Background summary

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 (CO_2) 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 CO_2 enriched ambient air and the use of the breath-actuated mode of the AeroEclipse II nebulizer with adjusted Tobramycin dose are evaluated.

Study objective

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.

Study design

Analysis at end of study.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Bronchiectasis;

2. Antibiotic inhalation therapy.

Exclusion criteria

1. Age <21 years;

2. Chronic respiratory insufficiency defined according to the GOLD criteria (PaO_2 < 60 mmHg or $PaCO_2$ > 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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2012
Enrollment:	14
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-04-2012
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	NL3255
NTR-old	NTR3407
Other	CWO : Pro12/15

Study results

Summary results

N/A