Gedrag van nasaal toegediende tobramycine en colistine in het lichaam van patiënten met taaislijmziekte

No registrations found.

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

Summary

ID

NL-OMON28674

Source
Nationaal Trial Register

Brief title
SPOEL study

Health condition

Cystic Fibrosis

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: Lungfund Haga Teaching Hospital

Intervention

Outcome measures

Primary outcome

- AUC (area under the curve);

- tmax (time to maximum concentration);

- Cmax (maximum plasma concentration);

- t1/2,el (terminal half-life);

- F (bioavailability).

Secondary outcome

- CL (total body clearance);

- safety of the nasal irrigations with tobramycin, colistin and a combination of tobramycin and colistin, determined by systemic absorption (bioavailability);

- adverse reactions;

- Visual Analogue Scale (VAS) score for (in)convenience of the nasal irrigations.

Study description

Background summary

The sinonasal area of patients with Cystic Fibrosis (CF) can be a reservoir for P. aeruginosa from which cross-infection to the lungs may occur. Specific antimicrobial treatment for P. aeruginosa in the sinonasal area is not yet developed. Accurate treatment of this pathogen in the sinonasal area can prevent or postpone cross-infection to the lungs and consequently chronic lung infections. Studies of the pharmacokinetics of nasally administered tobramycin and colistin were never performed. Safety of this treatment has to be established before intervention studies on the effect of these drugs on clinical parameters are initiated. Systemic absorption can be used as surrogate parameter for safety.

Objective: To investigate the clinical pharmacokinetics of tobramycin and/or colistin after nasal administration.

Study design: Intervention study.

Study population: Patients of 18 or older with a confirmed diagnosis of Cystic Fibrosis attending the outpatient clinic of the Adult Cystic Fibrosis Center, Haga Teaching Hospital.

Intervention: Each patient irrigates the nose with tobramycin mixed with isotonic saline once, colistin dissolved in isotonic saline once and tobramycin and colistin together dissolved in isotonic saline once. Each subject visits the hospital six times. During three of those visits six venous blood samples are taken (in total 18 bloodsamples).

Study design

Bloodsamples are collected at: t = 0, 0.5, 1, 2, 4, 6 hours after the nasal lavage.

Intervention

3 different types of nasal lavages: 1 = isotonic saline with tobramycin, 2 = isotonic saline with colistin, 3 = isotonic saline with tobramycin and colistin.
Each patient performs all three nasal lavages. No control group is necessary for this study. Patients perform each nasal lavage two times and for each nasal lavage the patient visits the hospital twice. The total duration of the study is 6 days.
For each type of nasal lavage 6 bloodsamples are taken, in which the concentration of the specific antibiotic is measured. With these data the farmacokinetics can be determined.

Contacts

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Eligibility criteria

Inclusion criteria

- Confirmed diagnosis of Cystic Fibrosis based on genotyping or a positive sweat test;

- Age > 18 years;

- Intravenous course of tobramycin in the past, but within the age of 18 years, with a creatinine value measured during that same intravenous course of tobramycin.

Exclusion criteria

- Kidney dysfunction (defined as estimated Glomerular Filtration Rate of < 50 ml/min);

- Liver dysfunction (defined as at least one of the following enzymes ¡Ý 3 times the normal value; aspartate aminotransferase (ASAT), alanin aminotransferase (ALAT), Gamma-glutamyltransferase (gGT), lactate dehydrogenase (LD) and alkaline phosphatase (ALP);

- Intravenous treatment with aminoglycosides or polymyxins 48 hours;

- Acute pulmonary exacerbation ;

- Allergy or intolerance for aminoglycosides or polymyxins;

- Recurrent epistaxis;

- Recent surgery of ear, nose or sinuses (< 3 months before study entry);

- Participation in another clinical trial within 30 days prior to study entry.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2013
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion
Date: 08-05-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38737
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3826
NTR-old	NTR4008
CCMO	NL43431.098.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38737

Study results

Summary results
N/A