Evaluating of tobramycin in lung after controlled inhalation of a radioactive solution containing tobramycin in patients with Cystic Fibrosis.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20058

Source
NTR

Brief title
DEPOSITIE

Health condition

Cystic Fibrosis, deposition study, Tc-DTPA, SPECT-CT, Inhalation flow manoeuvre, aerosol, radioactivity, Pulmonary drug delivery, nebulizer, 3D imaging, Ineb, CF, longdepositie, tobramycine

Sponsors and support

Primary sponsor: Haga Teaching Hospital and Central Hospital Pharmacy, The Hague.
Source(s) of monetary or material Support: NCFS (Nederlandse Cystic Fibrosis Stichting)

Intervention

Outcome measures

Primary outcome

Total lung deposition.

Secondary outcome

1. Location of deposition, defined as Penetration Index (PI);

2. Pharmacoketics: e.g.: systemic bioavailability of tobramycin after inhalation.

Study description

Background summary

In de depositiestudie vernevelen 18 CF patienten met verschilende ziektestadia 2 maal met een INeb een radioactief gelabelde tobramycine oplossing. Het ene bezoek staat de Ineb in TIM en het andere in TBM modus op basis van randomisatie. Naast SPECT-CT opnamen worden bloedmonsters afgenomen gedurende 24 uur. De volgende vragen worden onderzocht: hoeveelheid en locatie van depositie na een verneveling met de Ineb, relatie tussen Farmacokinetiek en locatie van depositie, invloed van de inhalatiemanoevre op de depositie, relatie tussen depositie en ziekteactiviteit.

Study objective

1. Inhaltion of tobramycin containing aerosols using the INeb® in the TBM mode is less effective as inhalation of in the TIM mode;

2. The amount of deposition is correlated to the systemic Area Under the Curve of tobramycin after inhaltion of tobrmaycin.

Study design

1. Total lung deposition: %deposition in lung (of activity (MBq) administered);

2. PI: Quotient of amount (MBq) central vs amount (MBq) periferic airways;

3. AUC_0-12 hr (based on serum tobramycin levels (mg/l)).

Intervention

inhaltion of solution containing tobramycin and TcDTPA.

Contacts

Public
Central Hospital Pharmacy The Hague
Escamplaan 900
Joris Uges
Den Haag 2547 EX
The Netherlands
Scientific
Central Hospital Pharmacy The Hague
Escamplaan 900
Joris Uges
Den Haag 2547 EX
The Netherlands

Eligibility criteria

Inclusion criteria

1. Clinical diagnosis of CF and a positive sweat test or two CF related mutations;

2. Adult patients aged 18 years and older;

3. Written informed consent;

4. Routine use of nebulized tobramycin;

5. Stable disease;

6. Patients must satisfy their medical examiner about their fitness to participate in the study;

7. Patients with no clinically significant abnormal serum biochemistry and haematology;

8. Female subjects with a negative pregnancy test, determined within 14 days of the start of the study and prior to each dosing phase.

Exclusion criteria

1. Pregnancy or lactation, women of childbearing potential must maintain effective contraception during the treatment period;

2. Acute exacerbation of pulmonary infection;

3. An FEV1 value which differs more than 10% from baseline value measured prior to the first dosing phase;

4. Use of any treatment within three days before the start of the study that may interfere with the effect to be studied;

5. Known impaired kidney function (serum creatinin > 177 umol/L corresponding with an estimated creatinin clearance < 60 ml/min.);

6. Patients receiving loop diuretics;

7. Intravenous use of tobramycin;

8. Treatment with any unregistered drug during the month prior to the administration of the investigational aerosol;

9. Current therapy or disease which may complicate the evaluation of the study protocol.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2010
Enrollment:	18
Type:	Actual

Ethics review

Positive opinion

Date:	20-10-2011
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	NL2962
NTR-old	NTR3109
Other	METC-ZWH : 07-049
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Laube, B.L., Jashnani, R., Dalby, R.N. et al. Targeting aerosol deposition in patients with cystic fibrosis. Effects of alterations in particle size and inspiratory flow rate. Chest 2000; 118:1069-1076.
Le Brun, P.P.H., Vinks, A.A.T.M.M., et al.. “Can tobramycin inhalation be improved with a jet nebulizer?” Ther Drug Mon.1999; 21:618-24.
Foster, W.M., Stetkiewicz, P.T., Freed, A.N.J. Retention of soluble 99mTc-DTPA in the human lung: 24-h postdeposition. Appl. Physiol.1997; 82:1378-1382.
Eberl, S., Chan, H.K., Daviskas, E., SPECT imaging for radioaerosol deposition and clearance studies. J. Aerosol Med. 2006; 19:8-20.
Touw, D.J., Graaf, A.I. de, Goede, P.N.F.C. de. Evaluation of a fluorescence polarographic immunoassay with increased sensitivity for measurement of low concentrations of tobramycin in serum. Ther Drug Mon 1996; 18:189-193.