TAPAS study in patients with CF

No registrations found.

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

Summary

ID

NL-OMON27235

Source
NTR

Brief title
TAPAS study in patients with CF

Health condition

Cystic Fibrosis
Tobramycin

Sponsors and support

Primary sponsor: Erasmus Medical Center - Sophia Children's Hospital
Source(s) of monetary or material Support: Erasmus Medical Center - Sophia Children's Hospital

Intervention

Outcome measures

Primary outcome

change in FEF75 (Z-score and L/s) after 4 weeks of targeted treatment

Secondary outcome

• Change in FEV1, FVC, FEF25, FEF50, MMEF25-75 (Z-scores and absolute values);

• Change in Lung Clearance Index (LCI) measurements as assessed by multiple breath washout;

• Change in Pa bacterial CFUs (defined as the log10 value for the number of Pa CFUs per millilitre of sputum, either expectorated or collected by suction of the oropharynx);
• Change in percentage of trapped air on MRI (% of total lung volume);

• Change in FEV1 before and after nebulisation (safety parameter);

• Systemic bioavailability of inhaled tobramycin, defined by trough level;

• Change in creatinine and blood urea nitrogen (BUN) values as measure of early renal toxicity;
• Change in hearing function (measured by HFPTA);
• Compliance rate;

• Patient satisfaction (use of device);

• Cystic Fibrosis questionnaire-revised (CFQ-R): respiratory symptoms scale scores and treatment burden scale scores.

Study description

Study objective

Inhalation of once daily double dose of inhaled tobramycin targeted to the small airways by the Akita (1x 300 mg instead of 2x 150 mg) is more effective in reducing small airways obstruction compared with standard of treatment: twice daily nebulization of standard dose using a standard nebulizer (2x 300 mg).

Study design

There will be 4 study visits in the outpatient clinic. The first and third study visit will be at the start of the treatment months, the 2nd and 4th study visits will be at the end of the treatment months.

Intervention

Patients will nebulize tobramycin during 2 months in a cross-over setting: 1 month nebulization with the Akita nebulizer (once daily 300 mg tobramycin instead of twice daily 150 mg) and 1 month the recommended dose with their own nebulizer (twice daily 300 mg tobramycin). The two treatment months are seperated with a month without treatment as recommended for the treatment of a chronic pseudomonas infection.

Contacts

Public

Dr. Molewaterplein (kamer Sp 3456) 60,

H.M. Janssens
Rotterdam 3015 GJ
The Netherlands
010-7036263

Scientific

Dr. Molewaterplein (kamer Sp 3456) 60,

H.M. Janssens
Rotterdam 3015 GJ
The Netherlands
010-7036263

Eligibility criteria

Inclusion criteria

• Age ≥ 12 years

• Clinical diagnosis of CF and a positive sweat test or two CF-related mutations;

• Chronic Pa colonization requiring maintenance therapy with inhaled tobramycin, defined according to the Leeds criteria (>50% Pa positive airway cultures over last 12 months) 22;
• Small airways obstruction present on spirometry (defined as follows: dissociation between FVC and FEF75 values (i.e. FEF75 at least 20% (absolute percent predicted) less than FVC);

• Ability to breathe through a mouthpiece and to use the inhaler;

• Ability to perform lung function tests;

• Written informed consent (12-18 years: child and parents; ≥ 18 years: patient).

Exclusion criteria

• Severe acute exacerbation of pulmonary infection (needing intravenous treatment) within one month prior to start or during the study;

• Known impaired kidney function (estimated creatinine clearance < 60 ml/min);

• Known aminoglycoside hypersensitivity;
• Start of nephrotoxic or ototoxic drugs, e.g. aminoglycosides, within 1 month prior to start or during the study;

• Therapy (e.g. furosemide) or disease which may complicate evaluation of the study protocol, as judged by the investigator;

• Participation in another drug-investigating clinical study at the start or within 1 month prior to the start;

• Inability to follow instructions of the investigator.

• Use of Tobramycin Inhalation Powder as part of the maintenance therapy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2015
Enrollment:	26
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-05-2015
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	NL5079
NTR-old	NTR5211
Other	: MEC-2014-260

Study results