Daily observation of inhalation of Tobramycine Inhalation Powder (TIP)

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24275

Source
Nationaal Trial Register

Brief title
TIPTIS study

Health condition

Cystic Fibrosis
Taaislijmziekte
Inhalationprofile
Inhalatieprofiel
Deposition
Depositie

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Gelden van dr Tiddens

Intervention

Outcome measures

Primary outcome

The main study parameter is the percentage of patients who inhale with a slow/ intermediate/ fast inhalation maneuver while inhaling TIP.

Secondary outcome

Secondary study parameters are: Difference in percentage of patients who react with cough immediately during or following TIP inhalation for the slow/intermediate/fast inhalation maneuver, prevalence of errors made in TIP inhalation in the home situation according to scoring items list, percentage of patients able to execute a slow and deep inhalation using TIP, and tidal volume pattern while patients are inhaling from a conventional nebulizer

Study description

Study objective

Patients in the home situation will mostly inhale forcefully through the TIP inhaler.

A forceful inhalation is associated with cough

A slow and deep inhalation using TIP results in a reduction of cough and more effective completion of a full inhalation maneuver

Patients inhale with a wide variation of tidal volumes while inhaling from a nebulizer

Study design

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Intervention

During the second home visit patients will be instructed to inhale as fast as possible, either the first or the second pair of four inhalations of tobramycin capsules. They will also be asked to inhale from a nebuliser with 0,9% NaCl solution for 10 minutes

Contacts

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Eligibility criteria

Inclusion criteria

Proven CF

Maintenance treatment with TIP

Age of 6 and older

Informed consent by parents or patients

Exclusion criteria

Respiratory tract exacerbation at time of TIP month defined as treatment with intravenous antibiotics

Any other acute condition such as otitis media which according to the treating physician will increase the risk of cough during the inhalation maneuvers.

Inability to follow instructions

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2015
Enrollment:	32
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 43918
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5080
NTR-old	NTR5212
CCMO	NL53582.078.15
OMON	NL-OMON43918

Study results