Assessment of real life and trained inhalation of Tobramycin Inhalation Powder (TIP) and Tobramycin Inhalation Solution (TIS) TIPTIS study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON43918

Source
ToetsingOnline

Brief title
TIPTIS study

Condition

- Respiratory disorders congenital
- Congenital respiratory tract disorders

Synonym
Cystic Fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: (Kinder)longziekten
Source(s) of monetary or material Support: Fondsen prof. H. Tiddens;Novartis,Novartis

Intervention

Keyword: Cystic Fibrois, Deposition, Inhalation profile

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

Background summary

Tobramycin inhalation powder (TIP) is recently introduced in treating Pseudomonas aeruginosa (Pa) infection in Cystic Fibrosis (CF) patients. Higher rates of sputum concentration are found compared to tobramycin inhalation solution. High inhalation flows are likely to lead to more oropharyngeal deposition of tobramycin. Compared to tobramycin inhalation solution (TIS), more patients report cough after the inhalation of TIP. Our hypothesis is that patients inhale TIP forceful, and that this leads to cough. A slow and deep inhalation should reduce cough and thereby allows a more effective completion of the full inhalation maneuver. We also hypothesize that patients inhale

with a wide variation of tidal volume when inhaling from a nebulizer.

Study objective

Primary objective of the study is to record TIP inhalations on video at home to study the association between inhalation manoeuver and cough.
Secondary objectives are: To study the inhalation maneuvers of patients using TIP in the home situation; to determine for TIP whether fast inhalations are associated with cough; to determine for TIP whether it is feasible to instruct patient to do a slow and deep inhalation; to determine the duration of the inhalation of TIP; to determine the tidal volume pattern while patients are inhaling from a conventional nebulizer; and to record inhalation profiles of TIP and nebulizer inhalations for later computer simulations using fluid dynamic modeling of aerosol deposition.

Study design

This is a prospective study. Patients will be observed on video using TIP and nebulizing NaCl solution in the home situation. During two home visits, every visit 4 inhalations of TIP will be recorded on video, and between the visits 3 unsupervised inhalations will be recorded. During the second visit patients will be asked to inhale either the first or second pair of tobramycin capsules forcefully using a cross-over design.

Study burden and risks

Patients will be visited at home twice to record inhalations on video and measure inhalation flows. The second visit patients will be asked to nebulise NaCl solution for 10 minutes and to inhale tobramycin forcefully twice. Between the home visits patients will be asked to record 3 unsupervised inhalations on video. The video registrations and flow recordings are not invasive. Participating children are used to nebulisation or inhalation therapy. During forceful inhalations cough might be triggered, if this cough occurs we expect it to be of short duration. Patients and parents will get feedback on the TIP inhalation technique during the routine outpatient visit following the study, which is likely to improve efficacy of the inhalation therapy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Proven Cystic Fibrosis
Maintenance treatment with TIP
Age 6 years or older
Informed consent by parents and/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 instrucgtions

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-11-2015
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	07-08-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-11-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24275
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL53582.078.15
OMON	NL-OMON24275