Hypertonic saline in Primary Ciliary Dyskinesia: a pilot study

No registrations found.

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

Summary

ID

NL-OMON22149

Source
NTR

Brief title
HS study

Health condition

Primary Ciliary Dyskinesia

Sponsors and support

Primary sponsor: VU University medical center
Source(s) of monetary or material Support: PCD patient organisation

Intervention

Outcome measures

Primary outcome

Primary research question:

- Is there a significant difference in change in the St. George’s Respiratory Questionnaire total and sub-scores (SGRQ) within intervention periods?

Secondary outcome

Secondary research questions:

- Are there significant differences in change in the Quality of Life score for bronchiectasis patients score (QoL-B) , lung function, lung clearance index, respiratory culture results, inflammatory parameters in sputum and blood and exacerbation frequency?

- What are the effect sizes of these differences in PCD patients?

Study description

Study objective

We hypothesize that bi-daily 5ml NaCl 7% nebulizations improve respiratory symptoms and quality of life in PCD patients compared to 5ml NaCl 0,9% nebulizations.

Study design

6 visits: baseline, 6 weeks, 12 weeks, 16 weeks, 22 weeks, 28 weeks.

Intervention

A: NaCl 7% nebulization with 0,25mg/ml quinine sulphate as taste masking agent

B: NaCl 0,9% nebulization with 0,25mg/ml quinine sulphate as taste masking agent

Contacts

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Eligibility criteria

Inclusion criteria

* Diagnosis of primary ciliary dyskinesia

* ≥ 18 years of age

* Capable of performing lung function tests.

* The forced expiratory volume in one second (FEV1), measured at screening, has to be within 10 % of the best value obtained during the previous six months and at least 40% of the predicted value for height, age and sex.

Exclusion criteria

* Smoking

* FEV1 < 40 %.

* Use of Pulmozyme or other mucolytics or non-routine antibiotics in the previous 30 days.

* A decline in lung function of more than 15 % or oxyhemoglobin of < 90% after test nebulization with hypertonic saline at screening visit

* Women with a current or intended pregnancy during the trial

* Diagnosis of quinine sulphate allergy

* Myasthenia Gravis

* Lambert-Eaton syndrome

* Optic neuritis

* Tinnitus

* Atrium fibrillation and other severe cardiac heart disease

* Epilepsy

* Glucose 6PD deficiency

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-07-2014
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	NL4498
NTR-old	NTR4674
Other	METC : 2013_198

Study results