Elite study.

No registrations found.

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

Summary

ID

NL-OMON23558

Source
NTR

Brief title
ELITE

Health condition

CF
pos. pseudomonas infection

Sponsors and support

Primary sponsor: chiron corporated ltd
generaal de witte laan 19a b5
2800 mechelen belgie
Source(s) of monetary or material Support: chiron corporated ltd
generaal de witte laan 19a b5
2800 mechelen belgie

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to estimate the duration of eradication of any strain of P aeruginosa infection during the 27 month study period following TNS treatment of early

infection in cystic fibrosis patients.

Secondary outcome

1. To estimate the proportion of subjects free form P aeruginosa at visit 5 with 300 mg twice daily for either 28 days or 56 days
to assess the safety of patients in the two treatment arms;

2. To assess the proportion of patients requiring hospitalisation for pulmonary exacerbation.

Study description

Background summary

Open label randomised multicenter observational study in the following treatment groups: 300 mg TNS given for 28 days and 300 mg TNS given for 56 days.

Study objective

To assess the duration of treatment (28 or 56 days) with inhaled tobramycine nebuliser solution of early onset pseudomonas infection in subjects with CF.

Study design

N/A

Intervention

- 5x blood sample

- 11x lungfunction testing

- 11x swabculture

- 4x audiology testing

Contacts

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Eligibility criteria

Inclusion criteria

1. Male or female subject > 6 months;

2. Diagnosis of CF;

3. First or early lower resp. tract infection with P aeruginosa.

Exclusion criteria

1. History of aminoglycoside hypersensitivity
symptoms of acute pulmonary disease
invest. drugs within 30 days prior to enrollment;

2. Abnormal result from audiology testing.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2003
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
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	NL340
NTR-old	NTR377
Other	: N/A
ISRCTN	ISRCTN80955954

Study results

Summary results
N/A