Elite study: the microbiological efficacy and safety of two treatment regimens of inhaled tobramycine nebuliser solution (TNS) for the treatment of early onset pseudomonas aeruginosa lower respiratory tract infection in subjects with cystic fibrosis

Submission date	Recruitment status	Prospectively registered		
19/12/2005	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/12/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
10/12/2009	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

NTR377

Study information

Scientific Title

Acronym

ELITE

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre randomised open label parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cystic fibrosis, Pseudomonas infection

Interventions

Treatment with inhaled tobramycine nebuliser solution (TNS) 300 mg twice daily for either 28 days or 56 days.

5 x blood sample, 11 x lung function testing, 11 x swab culture, 4 x audiology testing

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Tobramycine

Primary outcome(s)

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

Key secondary outcome(s))

- 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
- 2. To assess the safety of patients in the two treatment arms
- 3. To assess the proportion of patients requiring hospitalisation for pulmonary exacerbation

Completion date

30/09/2007

Eligibility

Key inclusion criteria

- 1. Male or female subjects greater than 6 months
- 2. Diagnosis of CF
- 3. First or early lower respiratory tract infection with Pseudomonas aeruginosa

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Αll

Key exclusion criteria

- 1. History of aminoglycoside hypersensitivity
- 2. Symptoms of acute pulmonary disease
- 3. Investigational drugs within 30 days prior to enrolment
- 4. Abnormal result from audiology testing

Date of first enrolment

01/10/2003

Date of final enrolment

30/09/2007

Locations

Countries of recruitment

Netherlands

Study participating centre Erasmus Medical Center

Rotterdam Netherlands 3015 GJ

Sponsor information

Organisation

Chiron Corporated Ltd (Belgium)

ROR

https://ror.org/05he4e720

Funder(s)

Funder type

Industry

Funder Name

Chiron Corporation Ltd (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2010		Yes	No