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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
19/12/2005

Registration date
19/12/2005

Last Edited
10/12/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Multicentre randomised open label parallel group trial

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
All

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