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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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 measures
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

Overall study start date
01/10/2003

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

Age group
Not Specified

Sex
Both

Target number of participants
120

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)

Sponsor details
Generaal de wittelaan 19a b5
Mechelen
Belgium
2800

Sponsor type
Not defined

ROR
https://ror.org/05he4e720

Funder(s)

Funder type
Industry

Funder Name
Chiron Corporation Ltd (Belgium)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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