ISRCTN80955954 https://doi.org/10.1186/ISRCTN80955954

# 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 |