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Voriconazole study: treatment of chronic endobronchial Aspergillus infection with voriconazole in patients 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	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/09/2008	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
NTR359

Study information

Scientific Title

Study objectives
Chronic infection with fungi seems to play an important role in the structural lung damage caused by inflammation. A correlation between Aspergillus specific IgG antibodies in the blood of cystic fibrosis (CF) patients and severity and extension of bronchiectasis was recently found in the CF-population treated at the Erasmus-MC.

Chronic infection with Aspergillus is seen in as much as 20% of CF patient of 5 years and older (Australian database, database CF-population Erasmus-MC/Sophia). These patients have positive sputum cultures for Aspergillus. The prevalence of chronic fungal infection seems to be increasing since the introduction of nebulised antibiotic treatment for Pseudomonas infection.

An effective treatment for chronic Aspergillus infection has not yet been found. The objective of this trial is to use voriconazole to treat patients with chronic endobronchial Aspergillus infection and CF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised double blinded, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cystic fibrosis (CF), Aspergillus infection

Interventions

Voriconazole versus placebo.

Analyses:
1. 7 x sputum culture
2. 7 x urine collection
3. 7 x blood sample
4. 7 x lung function
5. 1 x pregnancy test

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Voriconazole

Primary outcome measure
Is treatment with voriconazole in CF patients with a chronic Aspergillus infection effective?

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/03/2005

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of CF (documented by positive sweat test and/or by positive rectal current measurement, and/or genotype consistent with CF, two positive CF mutations, accompanied with two or more clinical features consistent with the CF phenotype)
2. At least three positive cultures for Aspergillus in the two years prior to the study
3. Positive galactomannan test at the start of the study
4. Older than 2 years of age

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants

Key exclusion criteria
1. Allergy to voriconazole
2. Use of drugs contraindicating use of voriconazole:
2.1. Terfanadine
2.2. Astemizol
2.3. Cisapride
2.4. Pimozide
2.5. Kinidine
2.6. Rifampicide
2.7. Carbamazepine
2.8. Phenobarbital
2.9. Ergotamine alkaloiden
2.10. Sirolimus
3. Use of liposomal amphotericine B
4. Use of high dose prednisone
5. Inability to produce sputum
6. Poor compliance
7. Pregnancy

Date of first enrolment
30/03/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3015 GJ

Sponsor information

Organisation
Erasmus Medical Centre (The Netherlands)

Sponsor details

Sophia Children's Hospital
Dr. Molewaterplein 60
Rotterdam
Netherlands
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Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/content/englishindex.htm

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Industry

Funder Name
Pfizer (The Netherlands)

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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