

Voriconazole study: treatment of chronic endobronchial Aspergillus infection with voriconazole in patients with cystic fibrosis

Submission date 19/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 19/12/2005	Overall study status Completed	☐ Protocol
Last Edited 16/09/2008	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised double blinded, placebo controlled, parallel group trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

1. Allergy to voriconazole
2. Use of drugs contraindicating use of voriconazole:
 - 2.1. Terfenadine
 - 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)

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, Pfizer Inc

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary