

Voriconazole study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28850

Source

NTR

Brief title

N/A

Health condition

CF patients with Aspergillus infection.

Sponsors and support

Primary sponsor: erasmusmc sophia

Source(s) of monetary or material Support: Pfizer pharmac group

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

N/A

Study description

Background summary

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 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.

Study objective

N/A

Study design

N/A

Intervention

7x sputumculture;
7x urine collection;
7x bloodsample;
7x lungfunction;
1x pregnancytest.

Contacts

Public

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Eligibility criteria

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.

Exclusion criteria

1. Allergy to voriconazole;
2. Use of drugs contraindicating use of;
 - a. Voriconazole;
 - b. Terfanadine;
 - c. Astemizol;
 - d. Cisapride;
 - e. Pimozide;
 - f. Kinidine;

- g. Rifampicide;
 - h. Carbamazepine;
 - i. Fenobarbital;
 - j. Ergotamine alkaloids;
 - k. Sirolimus;
3. Use of liposomal Amphotericin B;
 4. Use of high dose Prednisone;
 5. Inability to produce sputum;
 6. Poor compliance;
 7. Pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2005
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion

Date: 12-09-2005

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL321
NTR-old	NTR359
Other	: N/A
ISRCTN	ISRCTN35866380

Study results

Summary results

N/A