# Randomised, placebo controlled trial of itraconazole in the treatment of fungal sensitised patients with severe asthma and without allergic bronchopulmonary aspergillosis (ABPA)

Submission date	Recruitment status No longer recruiting	Prospectively registered		
26/09/2005		Protocol		
Registration date	Overall study status	Statistical analysis plan		
21/11/2005	Completed	[X] Results		
<b>Last Edited</b> 28/10/2008	Condition category Respiratory	[] Individual participant data		

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof David Denning** 

#### Contact details

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# Additional identifiers

# Protocol serial number

N/A

# Study information

#### Scientific Title

#### Acronym

**FAST** 

#### **Study objectives**

Itraconazole is effective as an adjunctive treatment in the treatment of severe asthma patients with skin test positivity for one of five fungal aero-allergens, who do not satisfy the criteria for ABPA.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

## Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Severe asthma with allergy to mould

#### Interventions

Itraconazole versus placebo

#### Intervention Type

Drug

#### Phase

**Not Specified** 

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

Itraconazole

#### Primary outcome(s)

To assess whether antifungal treatment with itraconazole is beneficial in the management of severe asthma

## Key secondary outcome(s))

1. To investigate whether there are subsets of patients who particularly benefit, or do not benefit from antifungal treatment

- 2. To determine whether any benefit of itraconazole is related to steroid interaction
- 3. To archive DNA for molecular genetic studies

#### Completion date

30/06/2006

# **Eligibility**

#### Key inclusion criteria

Asthma requiring: high dose inhaled steroids or continuous steroids or at least 4 courses oral /intravenous (IV) steroids over previous 12 months or at least 6 courses oral/IV steroids over the previous 24 months

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

- 1. ABPA (IgE >1000, precipitins positive)
- 2. Recurrent bacterial chest infections
- 3. Allergy to Azoles
- 4. Pregnancy
- 5. Current treatment with drugs that interact with itraconazole and which cannot be stopped
- 6. Significant cardiac disease
- 7. Significant immunosuppression other than corticosteroids
- 8. Abnormal liver function tests

#### Date of first enrolment

05/10/2004

#### Date of final enrolment

30/06/2006

# Locations

#### Countries of recruitment

United Kingdom

England

Study participating centre
ATR 4 Education & Research Centre
Manchester
United Kingdom
M23 9LT

# Sponsor information

#### Organisation

South Manchester University Hospitals NHS Trust (UK)

#### **ROR**

https://ror.org/00he80998

# Funder(s)

### Funder type

Charity

#### **Funder Name**

The Moulton Charitable Trust (UK)

# **Results and Publications**

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	01/01/2009		Yes	No