

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

Submission date 26/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/11/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 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

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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