ISRCTN61552714 https://doi.org/10.1186/ISRCTN61552714

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/11/2005	**Overall study status** Completed	
Last Edited 28/10/2008	**Condition category** Respiratory	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
05/10/2004

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

Age group
Adult

Sex
Both

Target number of participants
100

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
England

United Kingdom

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

Sponsor information

Organisation
South Manchester University Hospitals NHS Trust (UK)

Sponsor details
Wythenshawe Hospital
Southmoor Rd
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rdsec@fsl.with.man.ac.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type

Charity

Funder Name
The Moulton Charitable Trust (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/01/2009		Yes	No