

Study of the effectiveness of voriconazole in the treatment of *Aspergillus fumigatus* associated asthma

Submission date 21/11/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/01/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/02/2016	Condition category Respiratory	<input type="checkbox"/> 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

Study information

Scientific Title
Study of the effectiveness of voriconazole in the treatment of *Aspergillus fumigatus* associated asthma: a randomised double blinded, placebo controlled trial

Acronym
EVITA3

Study objectives

Voriconazole will be effective in eradicating colonisation of the airways by *Aspergillus fumigatus* (AF) in patients with *Aspergillus fumigatus* associated asthma (AFAA) and this will result in a prolonged improvement in their disease control.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leicestershire, Northamptonshire & Rutland Research Ethics Committee 2, REC No. 09/H0402/63

Study design

Randomised double-blinded placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Asthma

Interventions

12 month randomised double-blind placebo-controlled parallel group trial to receive either placebo or voriconazole 200 mg twice daily orally for 12 weeks.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Voriconazole

Primary outcome(s)

The number of severe exacerbations over the 12 months of the study.

Key secondary outcome(s)

1. The percentage of patients whose sputum is no longer AF positive after three months of treatment with voriconazole and at the end of the study
2. The change in the sputum eosinophil count (measured as area under the curve) in the voriconazole versus the placebo group after three months of treatment and at the end of the study
3. The change in the total sputum neutrophil count (measured as area under the curve) in the voriconazole versus the placebo group after three months of treatment and at the end of the study
4. The change in forced expiratory volume in one second (FEV1) between the treatment and placebo group after treatment and at the end of the study

5. The number of courses of antibiotics between the treatment and placebo groups
6. The improvement in Juniper Asthma Control Questionnaire (JACQ) score at the end of the treatment and at the end of the study

Completion date

08/07/2013

Eligibility

Key inclusion criteria

1. Symptoms consistent with a diagnosis of asthma
2. A clinical phenotype consistent with AF associated asthma in the opinion of at least two consultant members of the study team
3. Evidence of immune sensitisation to AF (either positive AF IgE, positive SPT to AF or positive AF IgG)
4. A raised peripheral blood eosinophil count or sputum eosinophil count of more than 10% on at least one occasion in the last two years
5. AF in sputum on two occasions within the six months prior to entry into the study
6. At least two severe exacerbations in the previous 12 months (defined as a requirement for a course of high dose oral steroids for treatment of their asthma)
7. Aged above 18 years, both male and female

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Unable to give informed consent
2. Pregnancy or possibility of becoming pregnant during the treatment phase of the study
3. A primary diagnosis (in the opinion of the study team) of chronic obstructive pulmonary disease (COPD) (smoking related obstructive disease)
4. Any conditions or drug interactions that in the opinion of the study team could lead to harmful interactions with voriconazole
5. Allergy to voriconazole
6. Poor compliance
7. Inability to produce sputum

Date of first enrolment

01/02/2009

Date of final enrolment

08/07/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Glenfield Hospital

Leicester

United Kingdom

LE3 9QQ

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

ROR

<https://ror.org/02fha3693>

Funder(s)

Funder type

University/education

Funder Name

University of Leicester (UK)

Alternative Name(s)

UniofLeicester, UoL

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2014		Yes	No
HRA research summary			28/06/2023	No	No