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

Submission date 21/11/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/01/2009	**Overall study status** Completed	
Last Edited 08/02/2016	**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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/02/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

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
England

United Kingdom

Study participating centre
Glenfield Hospital
Leicester
United Kingdom
LE3 9QQ

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details

c/o Professor Andrew Wardlaw
Glenfield Hospital
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England
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Sponsor type
Hospital/treatment centre

Website
http://www.le.ac.uk/external/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
University/education

Funder Name
University of Leicester (UK)

Alternative Name(s)
UoL

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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	01/07/2014		Yes	No
HRA research summary			28/06/2023	No	No