ISRCTN85866583 https://doi.org/10.1186/ISRCTN85866583

Early diagnosis of invasive aspergillosis

Submission date 19/05/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 19/05/2010	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 14/03/2017	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-2-new-tests-to-diagnose-a-fungal-infection

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2242

Study information

Scientific Title
Early diagnosis of invasive aspergillosis in a high risk group of patients using serum and bronchoalveolar lavage fluid, real time polymerase chain reaction (PCR) and galactomannan enzyme-linked immunosorbent assay (ELISA)

Study objectives

The aim of the study is to determine characteristics for two diagnostics tests in invasive aspergillosis (IA) in patients at high risk with neutropenia following intensive chemotherapy or allogenic bone marrow transpant.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East London and the City Research Ethics Board, 01/06/2005, ref: 05/Q0603/68

Study design
Single centre observational diagnosis and validation of investigative/therapeutic process study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Lung Cancer; Disease: Miscellaneous

Interventions
Study interventions will begin prior to the start of chemo/immunosuppression and continue until recovery of the neutrophil count to greater than 1.0 x 10^9/L. If fungal infection occurs, then testing should continue until discharge. Samples will be analysed in batches. A febrile episode is defined as any of the following:
1. Temperature greater than 38°C for more than 4 hours
2. Temperature greater than 38°C on two occassions greater than 4 hours apart within a 24 hour period
3. Temp greater than 38.5°C on one occassion

PCR: PCR for fungal DNA will be performed twice weekly.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
GM ELISA from serum and BALF, measured within 6 months of the conclusion of the study

Key secondary outcome(s))
Measured within 6 months of the conclusion of the study:
1. To establish cut off points to rule IA in or out
2. GM Elisa in prognosis
3. Inflamatory marker and cytokine profil in EBC
4. Non-invasive EBC in IA
5. PCR for Aspergillus
6. PCR for Aspergillus from blood and BALF

7. Repeated measures over time or a combination of markers
8. Role of BAL

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Informed consent
2. Patients with acute myeloid leukemia (AML), myelodysplastic syndromes (MDS) and acute lymphoblastic leukemia (ALL) undergoing intensive chemotherapy (predicted neutropenia of less than 0.5 x 10^9/L for greater than 10 days) and/or receiving high dose steroids
3. Patients undergoing allogeneic haematopoietic stem cell transplantation (HSCT)
4. Patients requiring high dose steroids for graft versus host disease post HSCT
5. Patients with a history of probable or proven invasive aspergillosis and having chemotherapy, regardless of their underlying haematological malignancy
6. Aged greater than 18 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Inability to give informed consent
2. Patients aged less than 18 years
3. Pre-existing chest disease

Date of first enrolment
01/06/2005

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ground Floor, Pathology Block
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Barts and The London NHS Trust (UK)

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Industry

Funder Name
Gilead Sciences Inc (USA)

Funder Name
Pfizer (UK)

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary