

# Early diagnosis of invasive aspergillosis

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
19/05/2010	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
19/05/2010	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
14/03/2017	Cancer	<input type="checkbox"/> 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

### Contact name

Mrs Denise Andrews

### Contact details

Ground Floor, Pathology Block  
St. Bartholomews Hospital  
West Smithfield  
London  
United Kingdom  
EC1A 7BE

## 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 transplant.

### **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  $1.0 \times 10^9/L$ . 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  $38^{\circ}C$  for more than 4 hours
2. Temperature greater than  $38^{\circ}C$  on two occasions greater than 4 hours apart within a 24 hour period
3. Temp greater than  $38.5^{\circ}C$  on one occasion

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. Inflammatory 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  $0.5 \times 10^9/L$  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

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes