

# The Pleural Infection Longitudinal Outcome Study

<b>Submission date</b> 20/03/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/05/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/06/2021	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This observational study aims to determine the capacity of baseline clinical and biological parameters and an associated prediction model (RAPID score) to predict mortality from pleural infection (infection of the membrane that enfolds the lungs).

### Who can participate?

Patients diagnosed with a pleural infection will be invited to participate.

### What does the study involve?

This study has been specifically designed to collect clinical and biological data - for example, the results of blood tests and pleural fluid analysis, and physical observations such as blood pressure, chest X-rays, chest ultrasound scans, lung function testing - in patients with diagnosed pleural infection. We hope that by analysing these results a diagnostic tool (or prediction score) can be developed that will help doctors in the future identify which patients with pleural infection are at higher or lower risk of serious problems or complications. This will hopefully help doctors choose the best treatment options for their patients.

### What are the possible benefits and risks of participating?

We hope that every patient in the study will benefit, as normal, from the treatment they receive for their pleural infection as well as the opportunity for regular and continued follow-up appointments and assessments. Participation in the study will not however entitle patients to receive any specific or specialist treatment that they might not otherwise have access to. When the study is completed, we hope that the information collected from those individuals who choose to participate will help us to improve the treatment of patients with pleural infection in the future. Pleural infection itself and the different methods of treating it have their own associated risks and complications, but none of these are affected by participation in this study. Patients will have at least three chest x-rays during their participation, although many of these would need to be done whether you were in the study or not. There are some theoretical health risks from excessive radiation exposure, but chest x-rays are considered one of the safest tests as the dose from one is only equivalent to around four days' worth of normal background radiation.

Where is the study run from?

The study is being led and co-ordinated by the Oxford Respiratory Trials Unit based at the Churchill Hospital, Oxford, United Kingdom.

When is the study starting and how long is it expected to run for?

In total, 500/600 patients from hospitals around the world will participate in this study over an approximate three year period starting in 2013.

Who is funding the study?

Medical Research Council (UK).

Who is the main contact?

Mrs Emma Hedley

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Najib Rahman

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 1.0 20/03/2013

## Study information

### Scientific Title

The Pleural Infection Longitudinal Outcome Study: an observational cohort study

**Acronym**

PILOT

**Study objectives**

An observation study to ascertain the capacity of baseline clinical and biological parameters and an associated prediction model (RAPID score) to predict mortality from pleural infection at 3 months.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee South Central - Oxford B, 11/07/2013, REC ref: 13/SC/0204

**Study design**

Observational cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**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**

Pleural Infection

**Interventions**

Demographics, details of clinical history and past medical history, drug history including antibiotic use within the last 4 weeks and baseline clinical observations, as recorded in normal clinical care. Baseline blood parameters (e.g. full blood count, inflammatory markers, renal function) and measurement of pleural fluid parameters (protein, glucose, LDH and pH if not purulent fluid, standard pleural fluid microbiology), chest X-ray and 10mL (0.3floz) of blood and 20mL (0.6floz) of pleural fluid will be obtained at enrolment into the study and stored in individual local centres.

Patients will be followed up at 3 and 12 months post trial entry.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

The primary outcome of this study is the capability of the prediction score (RAPID) to predict mortality from pleural infection at 3 months.

The PILOT study is intended to ascertain the capacity of baseline clinical and biological parameters and an associated prediction model (RAPID score) to predict key clinical outcomes including mortality from pleural infection. These include renal indices, age, purulence of pleural fluid, infection source and albumin measured at baseline.

**Secondary outcome measures**

The secondary outcomes of this study are the capability of baseline clinical indices and the prediction score (RAPID) to predict the following:

1. Mortality from pleural infection at 12 months
2. Duration of hospital (in-patient) stay
3. Necessity for surgical fluid drainage over 12 months
4. Failure of medical treatment
5. Residual lung function impairment at 3 months

**Overall study start date**

01/05/2013

**Completion date**

31/10/2017

**Eligibility****Key inclusion criteria**

Adult patients, both male and female, aged 18 years or over with pleural infection as diagnosed by standard and internationally-accepted criteria as follows:

1. A clinical presentation compatible with pleural infection, AND
2. A pleural fluid collection that may or (rarely, according to clinical judgement) may not require drainage that meets at least one or more of the following criteria:
  - 2.1. Purulent
  - 2.2. Gram stain positive for bacteria
  - 2.3. Bacterial culture positive
  - 2.4. Acidic with a pH <7.2
  - 2.5. Low pleural fluid glucose <3mmol/L (<40mg/dL)
  - 2.6. CT evidence of pleural infection (consolidation of underlying lung with enhancing pleural collection on contrast-enhanced CT)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

550

**Total final enrolment**

546

**Key exclusion criteria**

1. Age <18 years
2. No pleural fluid available for analysis
3. Previous pneumonectomy on the side of pleural infection
4. Expected survival <3 months due to co-morbid disease
5. Inability to give informed consent

**Date of first enrolment**

01/05/2013

**Date of final enrolment**

01/01/2017

## **Locations**

**Countries of recruitment**

Australia

Belgium

England

Singapore

United Kingdom

United States of America

**Study participating centre**

**Oxford Respiratory Trials Unit**

Oxford

United Kingdom

OX3 7LE

## **Sponsor information**

**Organisation**

University of Oxford (UK)

**Sponsor details**

Oxford University Hospitals NHS Trust

Joint Research Office

Block 60

Churchill Hospital

Oxford

England

United Kingdom

OX3 7LE

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ctrjg@admin.ox.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.ox.ac.uk/>

**ROR**

<https://ror.org/052gg0110>

**Funder(s)****Funder type**

Research council

**Funder Name**

Medical Research Council

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**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?
<a href="#">Results article</a>	results	26/11/2020	10/12/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No