

The Pleural Infection Longitudinal Outcome Study

Submission date 20/03/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/05/2013	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/06/2021	Condition category Respiratory	☐ 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?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Observational

Study design

Observational cohort study

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Australia

Belgium

Singapore

United States of America

Study participating centre

Oxford Respiratory Trials Unit

Oxford

United Kingdom

OX3 7LE

Sponsor information

Organisation

University of Oxford (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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	26/11/2020	10/12/2020	Yes	No
HRA research summary			28/06/2023	No	No