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The Pleural Infection Longitudinal Outcome Study

Submission date
20/03/2013

Recruitment status
No longer recruiting

Registration date
20/05/2013

Overall study status
Completed

Last Edited
22/06/2021

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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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
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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?
Results article	results	26/11/2020	10/12/2020	Yes	No
HRA research summary			28/06/2023	No	No