Early Lung Cancer Identification and Diagnosis

The ELCID Trial: A feasibility randomised control trial looking at the effect on lung cancer diagnosis of giving a Chest X-Ray to smokers aged over 60 with new chest symptoms

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Background:
In 2010, lung cancer killed over 34,000 people in the UK. Compared with other countries, patients in the UK have more advanced stage at presentation and a lower rate of resections. Most commonly, lung cancer is diagnosed following symptomatic presentation to primary care. No screening programmes or biomarkers currently exist. Our hypothesis is that one option for achieving earlier stage diagnosis (and more curative resections) is to lower the threshold for referral for CXR. In this trial we test the effect of referral for CXR with a lower threshold of symptoms ('extra-NICE').

Objectives:

**PRIMARY**
- To determine the prevalence of ‘extra-NICE’ symptoms in patients consulting in UK general practice, the proportion of those who agreed to participate, the proportion of those that are diagnosed with lung cancer (and the best sources of routine data for capturing lung cancers)
- To determine: the best way to train GPs to identify and recruit eligible patients into the trial, the most effective method of presenting the trial (and randomisation) to patients, barriers to recruitment and how can we overcome them, the best measures of resource use to facilitate health economic analysis of the cost-effectiveness of ‘extra-NICE’
- For patients diagnosed with lung cancer: stage at diagnosis, performance status and the proportion of patients receiving radical treatments

**SECONDARY**

- To determine:
  - the best way to train GPs to identify and recruit eligible patients into the trial
  - the most effective method of presenting the trial (and randomisation) to patients
  - barriers to recruitment and how can we overcome them
  - the best measures of resource use to facilitate health economic analysis of the cost-effectiveness of ‘extra-NICE’
  - for patients diagnosed with lung cancer: stage at diagnosis, performance status and the proportion of patients receiving radical treatments

Intervention, Control, Randomisation:
In this study the threshold for a CXR for potential lung cancer symptoms has been lowered and called ‘extra-NICE’; this recommends a CXR if one has not been obtained within the previous three months, the patient is aged 60+, a smoker or ex-smoker, with 10 or more pack-years of smoking, and with:
- a new or altered cough of any duration reported to primary care
- increased breathlessness or wheezing (whether or not associated with purulent sputum)

Controls receive usual care (current NICE guidance). Patients are being individually remotely randomised.

Working Group:
A Working Group has taken place and identified the best way to train GPs and practice staff, and the most effective methods of presenting the trial to patients.

Nestled Qualitative Study:
We are undertaking a nested qualitative study to inform the feasibility of individually randomising patients to an urgent CXR or not. Interviews are being conducted with participants and primary care staff to assess and inform the procedures and tools used in the trial and to explore any barriers to recruitment and how to overcome them. Data will be analysed using the Framework approach.

Figure 1: ELCID Trial schema

- Conduct working groups with GPs and patients as to how to present trial and randomisation to patients
- Recruit and train GPs
- Patients assessed for eligibility by GPs. Eligible patients are current or ex-smokers, aged 60+ with 10 or more pack years of smoking and with at least one of the following:
  - a new or altered cough of any duration reported to primary care
  - increased breathlessness or wheezing (whether or not associated with purulent sputum)
- Individual randomisation
  - n=386
- Allocated to urgent CXR (n=193)
- Allocated to NICE guidance (n=193)
- 2 months: Follow-up with questionnaires (EQ-5D, HADS, ICECAP(O), CSRI) by post
- 12 months: Follow-up in routine data sets

Figure 2: Thresholds for referral for CXR

- Urgent CXR if:
  - Haemoptysis, or any unexplained persistent symptoms suggestive of lung cancer (that are lasting more than 3 weeks)
  - smokers or ex-smokers aged 60+ presenting with new or altered cough and/or breathlessness or wheezing

**PRESENTING BUT NOT MEETING ANY THRESHOLD**
- Presenting but not meeting any threshold

Figure 3: Patient Recruitment-accrual graph (as of 20-01-2014)


This trial is registered with Clinical Trials.gov number: NCT01344005