Wales Cancer Trials Unit

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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Chief Investigator: Professor Richard Neal
Recruitment start date: 1st October 2012
Number of Practices open: 21

Sponsor: Bangor University
Trial Funder: National Awareness and Early Diagnosis Initiative (NAEDI)
Number of patients recruited: 34

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 exist. Our hypothesis is that one option for achieving earlier stage diagnosis (and more curative resections) is for earlier investigation of symptoms. For lung cancer there is a simple, cheap and readily available diagnostic investigation – the Chest X-ray (CXR). NICE guidelines currently identify the qualifying symptoms that should trigger referral for a CXR. In this trial we test the effect of referral for CXR with a lower threshold of symptoms ('extra-NICE').

Figure 1: ELCID Trial schema

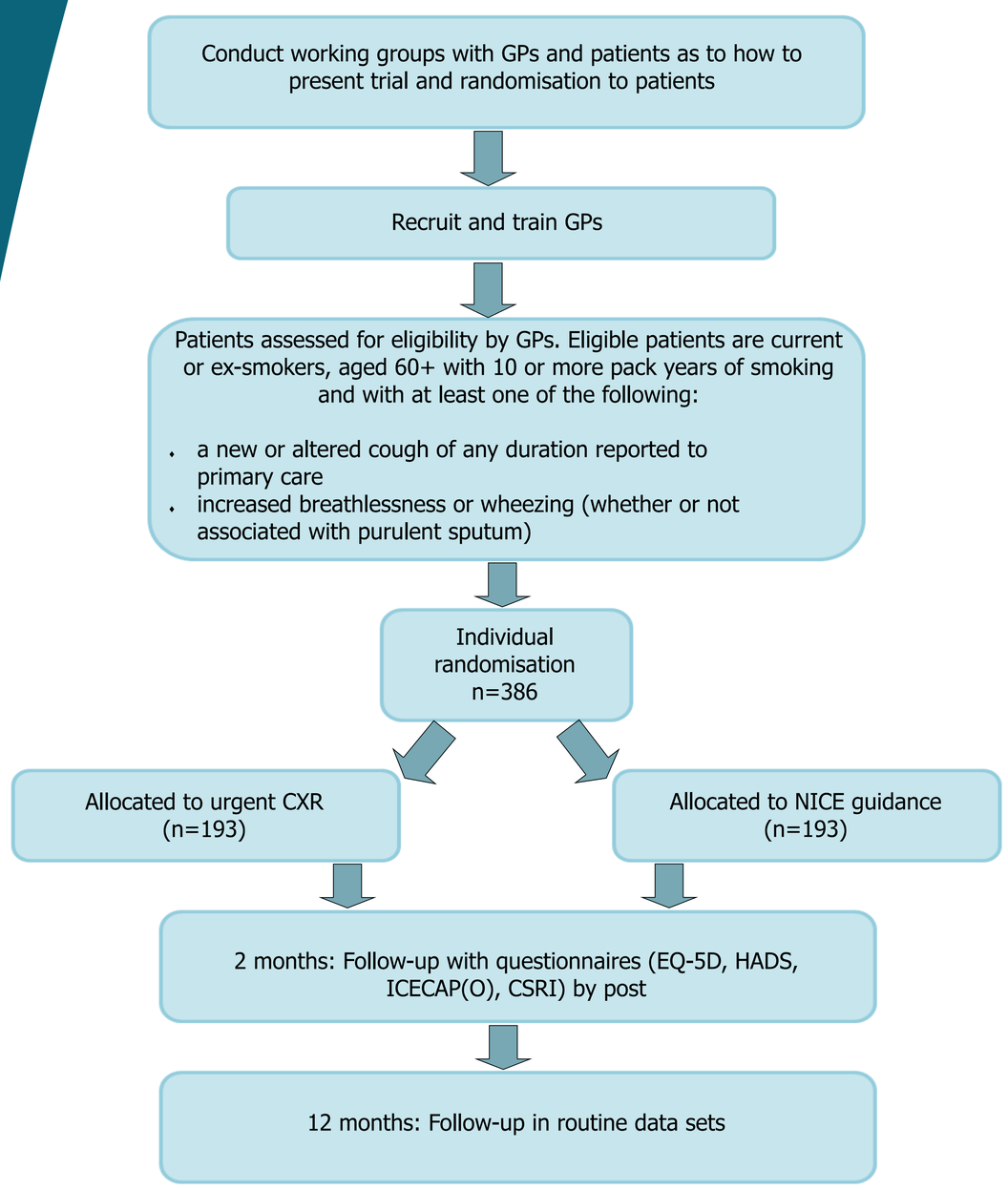
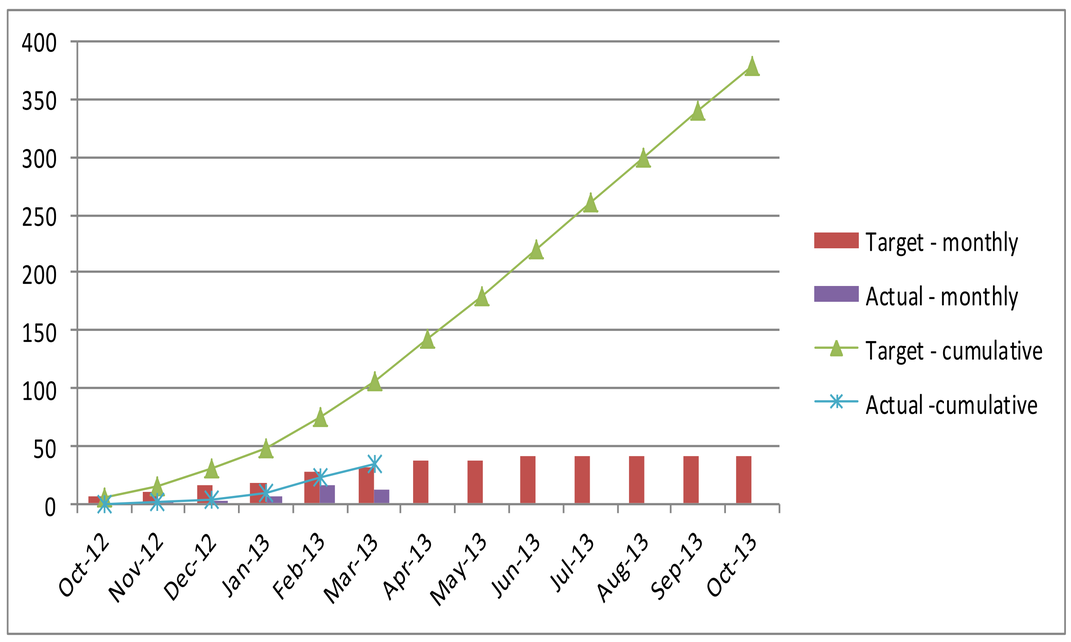


Figure 3: Patient Recruitment- accrual graph (as of 28-03-2013)



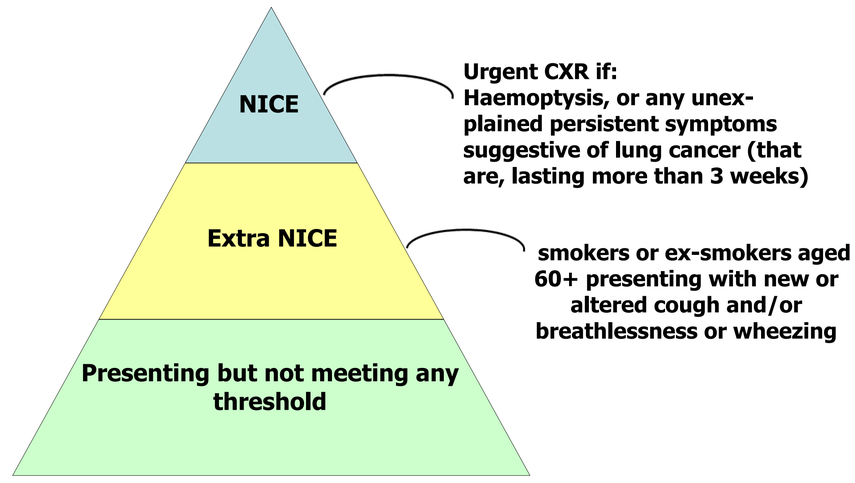
Objectives:
PRIMARY
To determine the prevalence of 'extra-NICE' symptoms in patients consulting in UK general practice, the proportion of those who agreed to participate, the proportion of those that are diagnosed with lung cancer (and the best sources of routine data for capturing lung cancers)

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
- and/or increased breathlessness or wheezing (whether or not associated with purulent sputum).

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

Figure 2: Thresholds for referral for CXR



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.

Nested 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.

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

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