and a range of psychological measurements. There is a nested qualitative study of the psychological effects test of results on participants. **Results:** In the first 14 months of recruitment 8 848 patients have been recruited and 9.0% of those tested have had a positive blood test with eight early cancers and 13 abnormalities undergoing further investigation detected to date in those who tested positive. Six of the eight cancers have been staged and four of these are early cancers. Provisional data reported to the trial team on those tested negative include three cancers. No data are currently available for the main trial comparison. From prior observational studies the test performance is expected to be: 40% sensitivity and 90% specificity these early data. Based on the study so far the current Positive Predictive Value of the test is 2.0%. **Conclusion:** The study will determine the EarlyCDT-Lung test's clinical and cost effectiveness. It will also assess potential morbidity arising from the test and potential harms and benefits of a negative EarlyCDT-Lung test result. Early results in the test only arm of the trial are encouraging.

BIOMARKERS AND LUNG NODULE MANAGEMENT
MONDAY, SEPTEMBER 7, 2015 - 16:45-18:15

MINI12.09 Progress with an RCT of the Detection of Autoantibodies to Tumour Antigens in Lung Cancer Using the Early CDT-Lung Test in Scotland (ECLS)

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Background: Since the majority of lung cancer cases are detected at a late stage the prognosis remains poor at present. The National Lung Screening Trial (NLST) reported 20% reductions in lung cancer mortality in 2011, however as a primary screening modality CT is expensive and may lead to significant morbidity in individuals whose tests are false positives. The EarlyCDT-lung test detects autoantibodies to proteins in the earliest stages of the disease with a specificity of 93%. Research question Does using the EarlyCDT-Lung test reduce the incidence of patients with late-stage lung cancer (3 & 4) or unclassified presentation (U) at diagnosis, compared with standard practice? **Methods:**We are conducting an RCT of 12 000 participants in areas of Scotland within the most deprived quintile of the population whose mortality from lung cancer is high by international standards. Adults aged 50 to 75 who are at 1.2% risk over the next 2 years are eligible to participate. They should also be healthy enough to undergo curative interventions. We will undertake a comparison of the EarlyCDT-lung test and follow-up imaging at six monthly intervals for 2 years with standard clinical practice. The primary outcome is the difference, after 24 months, between the rates of patients with stage 3, 4 or unclassified lung cancer at diagnosis. Participants who develop lung cancer will be followed-up via electronic record-linkage to assess both time to diagnosis and stage of disease at diagnosis. The secondary outcomes are cost-effectiveness,