

BioMILD trial demonstrates lung cancer screening using microRNA blood test enhance prevention effort

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Lung cancer screening efforts have accelerated in the last decade, with researchers showing that low dose CT screening is effective in reducing lung cancer mortality. Now, researchers in Milan report that using a blood test, accompanied by low dose CT screening, is safe and effective. The results were shared today at the IASLC 2019 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer.

The National Lung Screening Trial (NLST) showed that [lung cancer screening](#) by three annual rounds of low-dose computed tomography (LDCT) reduced [lung cancer](#) mortality. The Multicentric Italian Lung Detection (MILD) provided additional evidence that extended intervention beyond five years, with annual or biennial rounds, enhanced the benefit of low-dose CT screening.

Ugo Pastorino, MD, of the Istituto Nazionale dei Tumori Foundation and the lead researcher on the MILD trial, reports on results from a new trial, the bioMILD trial, which tested the additional value of blood microRNA assay at the time of LDCT on a large number of volunteers, with the aim of targeting next LDCT intervals on the basis of individual risk profile.

The bioMILD trial prospectively enrolled 4,119 volunteers at Istituto Nazionale Tumori of Milan with the median age of 60 years, median pack-years 42, current smokers 79% and females 39%. At the end of March 2019, a total of 11,012 LDCTs and 9,156 miRNA tests were performed, with an overall compliance at the 3-year LDCT of 93% and a median follow-up 4.2 years.

Pastorino had previously reported that that microRNA expression profiles in tumors and, for the first time, also in normal lung tissue, are

indicative of aggressive lung cancer development and that specific microRNA signatures can be identified in plasma samples of patients up to two years before spiral-CT detection of the disease.

The BioMILD trial offered a lung cancer screening program combining LDCT and blood microRNA assay to heavy smokers (current or former 10 years) aged 50-75 years. At baseline, LDCT and miRNA were tested independently with blind evaluation. According to LDCT and miRNA profile, different screening intervals were chosen for the following repeats, and participants with double negative LDCT and miRNA were sent to a 3-year interval.

Preliminary analysis showed a significantly higher lung cancer incidence and overall mortality in subjects with positive LDCT and/or miRNA at baseline. No detrimental effects on stage I lung cancer proportion, resection rates, or interval cancer incidence were observed in the group of subjects sent to 3-year LDCT repeat. Sensitivity and specificity analyses of LDCT and miRNA at baseline and subsequent screening rounds will be presented.

"BioMild showed that the combination of microRNA assay and LDCT is a valuable and safe tool to assess individual risk profile and reduce unnecessary LDCT repeats in lung cancer screening," said Dr. Pastorino.

Provided by International Association for the Study of Lung Cancer

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