



*“Italian lung cancer CT screening
trial workshop”
Pisa, March 3-4, 2011*



International workshop on randomized lung cancer screening trials. State of the art in Europe after early conclusion of the US National Lung Screening Trial

The European Lung Cancer Trials

The PISA Position Statement Pisa, Italy, March 4th 2011

In light of the positive results of the National Lung Screening Trial (NLST), the European randomized CT screening (EUCT) investigators held a workshop in Pisa (Italy) to achieve consensus and to develop a strategic plan of action with regard to the implementation of CT screening in Europe and the continuation of the randomized EUCT trials.

There are six randomized lung cancer screening trials in Europe: NELSON (NL, B), DLCST (DK), ITALUNG (I), DANTE (I), LUSI (D), MILD (I), in which in more than 32,000 subjects have been enrolled. One trial in the UK is in preparation (UKLS).

The shared opinion of the trial investigators is that all EUCT trials should continue and evaluate the full effect of low-dose CT screening as compared to no-screening (usual care), both in terms of the lung cancer and overall mortality reduction as well as their harmful side effects. The EUCT investigators agreed upon a combined interim analysis of the EUCT trials in 2012, while all trials will continue until their planned end, regardless of the outcome of this interim analysis.

There are many questions to be answered before lung cancer screening with low dose CT can be recommended to millions of current and former smokers.

The EUCT investigators and the scientists attending the Pisa Workshop suggested several questions that need to be answered in the near future, before considering implementation of low-dose CT screening for lung cancer:

- 1) What is the optimal target population for screening and how could we assess individual lung cancer risk, with the aim of selecting a population at higher risk?
- 2) Could early detection biomarkers play a role in individual lung cancer risk assessment?
- 3) What is the optimal management of CT detected suspicious nodules?
- 4) What is the optimal screening protocol (age range, screen interval, number of screening rounds, value of recall CT scans)?
- 5) What is the effect size of over-diagnosis?
- 6) What is the cost-effectiveness of CT screening?
- 7) What will CT screening add to an anti-smoking policy?
- 8) Is the efficacy of CT screening different in current versus former smokers?

Additionally, a recommendation in favor of screening for lung cancer should not rely on one single study. In fact, despite randomization, the population characteristics and the study design play a role in epidemiological studies and may influence the effect estimation.

The EUCT investigators stated as essential to implement primary prevention - especially smoking cessation and other anti-smoking policies - within screening policies.

In conclusion, the European trials should continue until their scheduled end, and in the meantime other demonstration projects, multi-centric and possibly coordinated at European level, should be



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implemented to evaluate critical aspects of the lung cancer screening process.

At individual level, spontaneous access to lung cancer screening should be discouraged at the moment, considering that the available evidence is still insufficient to suggest its use outside a controlled research setting.

In each case of spontaneous screening, exposure of subjects to CT screening requires careful information about the limited data available on the real benefit of screening on the one side, and the known harmful side effects on the other side. Therefore, a detailed written informed consent should be administered to every subject who volunteers for CT screening.