

# Gender effect in the ITALUNG screening trial. A comparison with UKLS and other trials

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The existence of gender differences in the efficacy of lung cancer (LC) screening with low dose CT is an interesting issue. In the meta-analysis associated with the mortality results of the UKLS trial, larger reductions of LC mortality were observed in females in the NELSON, NLST and LUSI trials, but not in the UKLS.<sup>1</sup> ITALUNG trial is a small size study that recruited 1132 women and 2074 men who were younger and predominantly current smokers as compared to those in UKLS,<sup>2</sup> and reported a 30% reduction of LC mortality in the active group.<sup>3</sup> After a follow-up extension of two years, the decreased LC mortality was 24%.<sup>4</sup> Herein we report gender effect in the ITALUNG extended follow-up dataset. Females showed a more pronounced LC mortality reduction (10 LC deaths during 6419 person-years in the active group and 16 LC deaths during 6076 person-years in the control group, resulting in a rate ratio of 0.59; 95%CI:0.27-1.30) than males (48 LC deaths during 11168 person-years in the active group and 58 LC deaths during 10975 person-years in the control group, resulting in a rate ratio of 0.81; 95%CI:0.56-1.19). The more pronounced benefit of LC screening in women was non statistically significant ( $p=0.477$ ). Reasons underlying the greater LC reduction in females participating to LC screening are unclear. Women have LC with a longer preclinical sojourn time, especially in case of adenocarcinoma, that would favour the possibility of screening detection.<sup>5</sup> Women might also be in healthier general conditions and have less co-morbidities.

## Declaration of interests

All the Authors of the manuscript declare not to have any conflict of interest.

## Contributions

Donella Puliti performed data collection, analysis and interpretation and wrote the article draft.

Giulia Picozzi performed data collection and participated to interpretation of the results and critically revised the manuscript.

Giuseppe Gorini supervised the data analysis and edited the manuscript.

Laura Carrozzi was involved in funding acquisition and study supervision and validation and critically revised and edited the manuscript.

Mario Mascalchi was involved in conceptualisation and methodology of the study, contributed to data interpretation and wrote the article draft.

## References

- 1 Field JK, Vulkan D, Davies MPA, et al. Lung cancer mortality reduction by LDCT screening: UKLS randomised trial results and international meta-analysis. *Lancet Regional Health - Europe* 2021;10:100179.
- 2 Mascalchi M, Lopes Pegna A, Carrozzi L, et al. Does UKLS strategy increase the yield of screen-detected lung cancers? A comparison with ITALUNG. *Thorax* 2016;71(10):950-1.
- 3 Paci E, Puliti D, Lopes Pegna A, et al. Mortality, survival and incidence rates in the ITALUNG randomised lung cancer screening trial. *Thorax* 2017;72(9):825-31.
- 4 Puliti D, Mascalchi M, Carozzi FM, et al. Decreased cardiovascular mortality in the ITALUNG lung cancer screening trial: Analysis of underlying factors. *Lung Cancer* 2019;138:72-8.
- 5 Ten Haaf K, van Rosmalen J, de Koning HJ. Lung cancer detectability by test, histology, stage, and gender: estimates from the NLST and the PLCO trials. *Cancer Epidemiol Biomarkers Prev* 2015;24(1):154-61.

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