

# Trial of metformin for non-small cell lung cancer

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Initial results of NRG-LU001 indicate that, although the diabetes agent metformin was well-tolerated by patients, the agent has not clearly improved progression-free survival (PFS) or overall survival (OS) for trial participants with locally advanced non-small cell lung cancer (NSCLC). These results are based on local center reported outcomes. Trial participants will continue to be followed for changes in their status. The initial report of these results were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting and the abstract was awarded a "Best of ASCO" designation.

"In previous pre-[clinical studies](#), metformin enhanced the response of human non-[small cell lung cancer](#) (NSCLC) models to radiotherapy and chemotherapy," stated Dr. Theodoros Tsakiridis, MD, Ph.D., of McMaster University and lead author of the NRG-LU001 abstract. "The pre-[clinical data](#) suggested a potential benefit for [patients](#) with lung cancer. For that, we pursued the NRG-LU001 trial to examine whether metformin could indeed improve outcomes in patients with stage III NSCLC treated with standard of care chemotherapy and radiotherapy."

In NRG-LU001 patients were randomly assigned either to the control arm that received standard chemotherapy and radiotherapy alone or to the experimental arm that received chemotherapy, radiotherapy, and 2000mg of metformin per day during those treatments. This study was designed to detect a 15% improvement in 12-month PFS from 50% to 65% or, equivalently, a HR of 0.622. Following treatment, researchers tracked the participating patients for changes in survival outcomes,

toxicities or side effects, time to local-regional progression (TTLRP), and time to distant metastasis (TTDM).

NRG-LU001 closed to accrual in December 2016 after completing accrual and randomization of the pre-planned number of 168 patients. There was no statistically [significant difference](#) in rates or grade of toxicity between the two arms, indicating that metformin was well-tolerated by patients. At the time of analysis, local centers reported 102 PFS events. The 1- and 2-year PFS rates were 60.4% (95% CI: 48.5, 70.4) and 40.1% (95% CI: 29.0, 51.0) in the control arm, and 51.3% (95% CI: 39.8, 61.7) and 34.5% (95% CI: 24.2, 45.1) in the experimental treatment arm with metformin. OS at 2 years was 65.4% (95% CI: 53.5, 75.0) in the control arm and 64.9% (95% CI: 53.1, 74.5) in the experimental arm (HR=1.03 (95% CI: 0.64, 1.68)). Deaths were due to lung [cancer](#) in 90% of the control arm and 71% of the experimental arm. These initial results of NRG-LU001 yielded no differences between treatment arms for TTLRP and TTDM.

"While finding no difference in the primary endpoint, between treatment arms was disappointing, we are heartened to observe better than expected PFS and OS rates in both arms of this study" said Dr. Heath Skinner, MD, Ph.D. of the UPMC Hillman Cancer Center who was Co-Principal Investigator of the trial, along with Dr. Tsakiridis. "We plan to complete secondary analyses with a central clinical and radiological review of all cases, as well as biomarker studies involving the biospecimens collected during this trial."

The results of NRG-LU001 demonstrate the value of continued investigation of NSCLC, one of the deadliest cancers worldwide, in multi-institutional settings such as NRG-Oncology.

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**More information:** Tsakiridis T\*, Hu C, Skinner H\*, Santana-Davila R, Lu B, Erasmus JJ, Doemer AJ, Videtic GMM, Coster J, Yang AX, Lee RY, Werner-Wasik M, Schaner PE, McCormack SE, Esparaz BT, McGarry RC, Bazan J, Struve T, Bradley JD. Initial reporting of NRG-LU001, randomized phase II trial of concurrent chemoradiotherapy (CRT) +/- metformin HCL in locally advanced Non-Small Cell Lung Cancer (NSCLC). Abstract presented at the annual meeting of the American Society of Clinical Oncology (ASCO). Chicago, IL.

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