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# RCT Abstract - Endosonography with or without confirmatory mediastinoscopy for resectable lung cancerA randomized clinical trial

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**Background** Resectable NSCLC with a high probability of mediastinal nodal involvement requires mediastinal staging by endosonography followed by mediastinoscopy according to current guidelines. However, the added value of confirmatory mediastinoscopy is under debate.

**Methods** We randomized patients with (suspected) resectable NSCLC and an indication for mediastinal staging (i.e. clinical N1-3 (cN) or a central, FDG-non-avid or peripherally located tumor >3cm on imaging) and a negative systematic endosonography to immediate lung tumor resection or confirmatory mediastinoscopy followed by tumor resection. The primary outcome in this non-inferiority trial (non-inferiority margin of 8%, $P_{non\text{-}inferior}$<.025) was the presence of unforeseen N2 disease following tumor resection with lymph node dissection. Secondary outcomes were 30-day major morbidity and mortality.

**Results** 360 patients were randomized, 178 to immediate lung tumor resection (7 drop-outs) and 182 to confirmatory mediastinoscopy first (7 drop-outs before and 6 after mediastinoscopy). Unforeseen N2 rate after immediate resection (8.8%) was non-inferior compared to mediastinoscopy first (7.7%) in both ITT (Δ:1.03%, UL 95%-CIΔ: 7.2%, $P_{non\text{-}inferior}$=0.0144) and PP (Δ:0.83%, UL 95%-CIΔ: 7.3%, $P_{non\text{-}inferior}$=0.0157) analyses. Major morbidity and 30-day mortality was 12.9% after immediate resection versus 15.4% after mediastinoscopy first (p=.49).

**Conclusion** Based on the non-inferiority margin in the rate of unforeseen N2, confirmatory mediastinoscopy after negative systematic endosonography can be omitted in patients with resectable NSCLC and cN1-3 or a central, FDG-non-avid or large (>3 cm) peripherally located tumor.