Navigational Bronchoscopy Versus Computed Tomography-guided Transthoracic Needle Biopsy for the Diagnosis of Indeterminate Lung Nodules: Initial Results From the VERITAS Multicenter Randomized Trial

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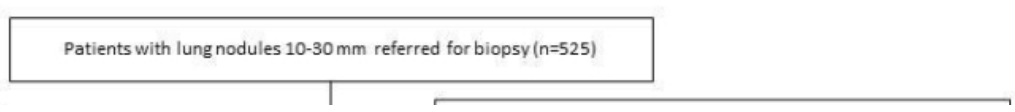
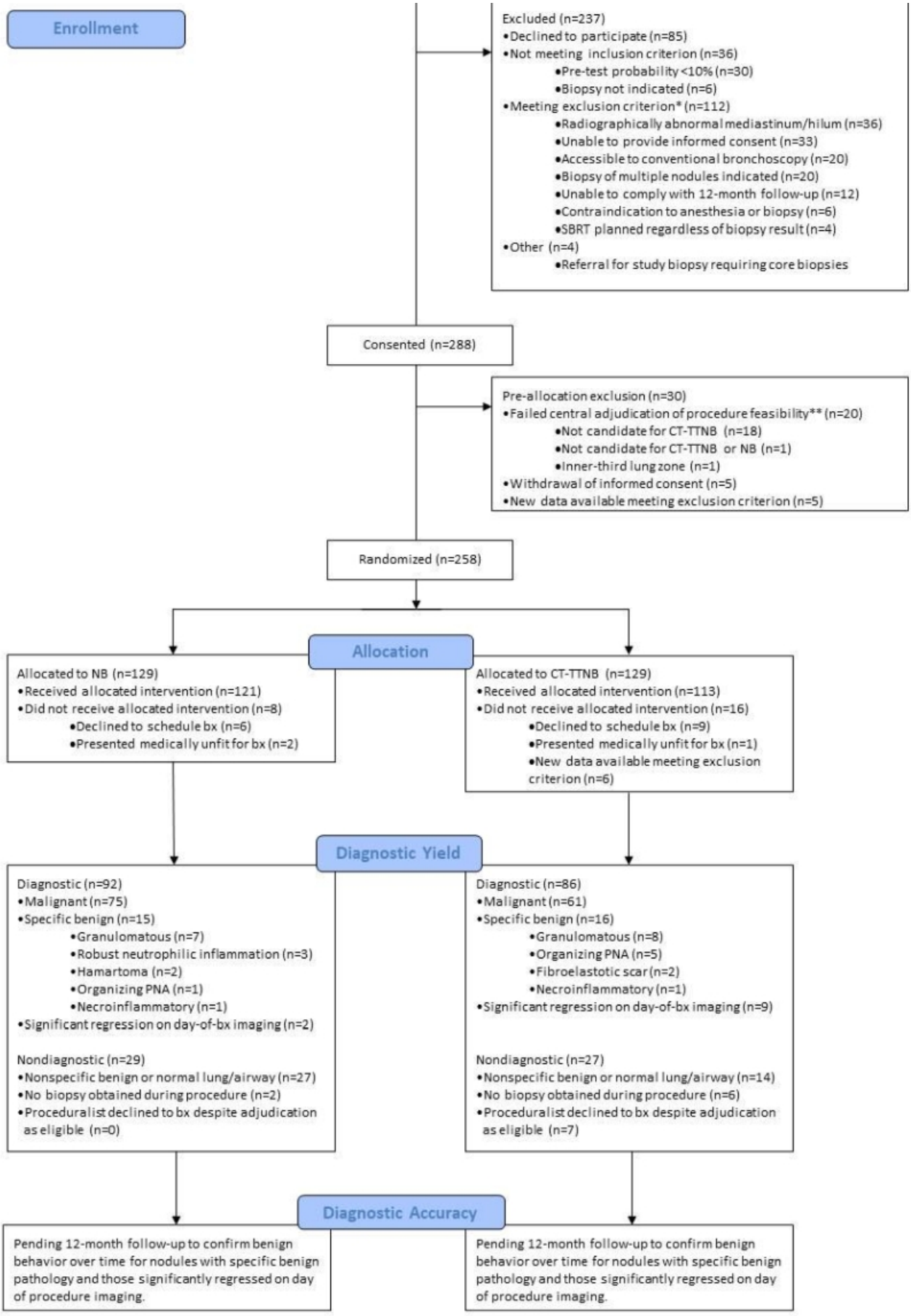
Background: Navigational bronchoscopy (NB) has not been compared to computed tomography-guided transthoracic needle biopsy (CT-TTNB) in a randomized controlled trial. CT-TTNB remains the gold standard for tissue diagnosis of indeterminate pulmonary nodules despite an associated 25% complication rate. The VERITAS trial is an investigator-initiated, multicenter, noninferiority randomized controlled trial comparing the clinical utility of NB to CT-TTNB. Methods: Patients with peripheral lung nodules 10-30 mm with pre-test probability of malignancy ≥10% determined to be technically accessible to both procedures by independent panels of bronchoscopists and interventional radiologists were randomized 1:1 to NB or CT-TTNB. The primary endpoint is diagnostic accuracy through 12 months of follow-up; secondary endpoints include diagnostic yield and safety. Primary analysis is per-protocol to be maximally conservative in the noninferiority context. We will conclude noninferiority if the probability that NB is worse than CT-TTNB by more than 10% is lower than 5% estimated using the posterior distributions. A strict definition of diagnostic yield was used in which biopsies were diagnostic only if specific histological findings explaining the presence of a nodule were present. All non-malignant biopsies were reviewed centrally with diagnostic adjudication by a panel of lung nodule experts blinded to biopsy technique. Results: Between 8/2021 and 6/2023, 258 patients at seven U.S. sites were randomized and 234 underwent biopsy procedures (Figure 1). Median nodule size was 15 mm (IQR 12-19); 88% (n=205) were in the peripheral third, 82% (n=193) were solid, and 33% (n=78) exhibited a bronchus sign. The primary outcome of diagnostic accuracy will be available Summer 2024. Per impending ATS consensus statement, diagnostic yield will be the recommended primary endpoint for diagnostic bronchoscopy studies. Accordingly, diagnostic yield, available now, is described below along with safety. NB was diagnostic in 92 of 121 patients (76%) while CT-TTNB was diagnostic in 86 of 113 (76%). The probability that NB was noninferior to CT-TTNB is 97%, exceeding the noninferiority threshold. Complications occurred in 31% of CT-TTNB (n=35) and 5.8% of NB procedures (n=7) (p<0.001). These included PTX requiring tube thoracostomy (8.8%, n=10 vs 0.8%, n=1), PTX not requiring thoracostomy (19.5%, n=22, vs. 2.5%, n=3), and hemorrhage (2.7%, n=3, vs. 0). Discussion: Navigational bronchoscopy was noninferior to CT-TTNB for the diagnosis of lung nodules, with a much better safety profile. Given these findings plus additional advantages including the ability to simultaneously perform mediastinal staging, bronchoscopy should be preferred to CT-TTNB for the diagnosis of indeterminate pulmonary nodules.

Figure 1. Trial Flow.





*Summed numbers exceed 112 as some patients met multiple exclusion criteria.
**Central adjudication performed by independent panels of central interventional pulmonologists (determining technical feasibility of NB) and interventional radiologists (determining technical feasibility of CT-TTNB), as well as standardized segmentation of lung zones to exclude inner-third nodules.

This abstract is funded by: Medtronic (unrestricted research grant)