# ^{18}F-PSMA-1007 PET/CT Versus Multiparametric MRI for the Locoregional Staging of Prostate Cancer: A Phase II Prospective Validating Paired-Cohort Trial

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## ABSTRACT

BACKGROUND:
Prostate-specific membrane antigen (PSMA) demonstrates overexpression in prostate cancer and correlates with tumor aggressiveness. PSMA positron emission tomography (PET) has been shown to be superior to conventional imaging for the metastatic staging of prostate cancer. The objective of this study was to determine the accuracy of ^{18}F-PSMA-1007 PET/CT compared to multiparametric magnetic resonance imaging (MRI, the current gold standard) in the primary locoregional staging of intermediate- and high-risk prostate cancers.

METHODS:
The Next Generation Trial (NCT05141760) was a Phase II prospective validating paired-cohort trial assessing ^{18}F-PSMA-1007 PET/CT and MRI for locoregional staging of prostate cancer, with final histopathology as the gold standard comparator in 134 patients undergoing prostatectomy. Radiologists, nuclear medicine physicians, and pathologists were blinded to preoperative clinical, pathology, and imaging data. The primary outcome was correct identification of the prostate cancer tumor ('T') stage. The secondary outcomes were correct identification of the dominant nodule, laterality, extracapsular extension, and seminal vesical invasion.

RESULTS:
PSMA PET was superior to MRI for the accurate identification of the final pathological T stage (45% vs. 27%, p=0.002). PSMA PET was also superior to MRI for the correct identification of the dominant nodule (94% vs. 83%, p=0.007), laterality (64% vs. 46%, p=0.001), and extracapsular extension (75% vs. 62%, p=0.005), but not for seminal vesicle invasion (91% vs. 83%, p=0.07).

CONCLUSION:
In this trial, ^{18}F-PSMA-1007 PET/CT was superior to MRI for the locoregional staging of prostate cancer. These findings support the use of PSMA PET in the preoperative workflow of intermediate- and high-risk tumors.