Phase 3 study of ^{68}Ga-PSMA-11 PET combined with MRI for the detection of prostate cancer (BIPASS)

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Background: Prostate cancer is the 2nd most common cancer in the USA and is diagnosed through directed and template/anatomical biopsy based on clinical and radiographic suspicion. In patients presenting with high risk of prostate cancer, anatomically-directed biopsies are performed to identify occult disease, which can lead to anxiety, complications, financial burden, and logistical challenges. Biopsy of the Prostate Avoidance Stratification Study (BIPASS) is a Phase 3 study evaluating the diagnostic performance of combining ^{68}Ga-PSMA-11 PET and MRI targeted biopsy for the detection of PCa, using histopathological confirmation as the standard of truth.

Methods: This Phase 3, single-arm, multicenter, prospective, open-label, longitudinal study (NCT07052214) will enroll up to 350 patients ≥18 years with clinical suspicion of PCa who have not undergone prior prostate biopsy and are scheduled to undergo template biopsy based on initial MRI within 3 months before enrollment (PI-RADS 1-4). Key exclusion criteria include prior treatment of PCa, diagnosis of PCa, or obvious metastatic disease on prior imaging.

All patients will undergo ^{68}Ga-PSMA-11 & MRI scans, followed by standard template biopsy. PSMA and MRI scans will be interpreted by 3 blinded readers. MRI- & PSMA-targeted biopsies will be performed with 2 cores per lesion. If PCa is histopathologically identified, lesion linking with imaging will be performed with no further follow-up required. Follow-up data will be collected for up to 6m for patients with no baseline imaging or histopathological evidence of PCa. Additional imaging & targeted biopsies may be performed during follow-up period at investigator discretion. Any additional biopsy, imaging, clinical, histological, genetic, & intervention data will contribute to the determination of the SOT. Follow-up will provide longitudinal surveillance to ensure that patients initially evaluated as negative for csPCa on both imaging & histopathology are reliably negative.

The co-primary endpoints are sensitivity and specificity of combining PSMA PET- & MRI- for the detection of csPCa, calculated by comparing diagnostic findings to histopathological or composite SOT. Key secondary endpoints include detection performance (sensitivity, specificity, PPV, NPV, accuracy, & misclassification rate) of PSMA PET & MRI for the detection of csPCa & interobserver variability of PSMA PET interpretation.

Results: This study is ongoing; no results are available at the time of abstract submission.

Conclusions: PSMA PET combined with MRI for may improve the detection of clinically significant PCa and treatment management, minimize cost and procedural risk, de-escalate the number of biopsies, and potentially eliminate the need for systematic/template/saturation biopsies in select populations.

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