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 (PCa) 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 PCa, 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 single-arm, multicenter, prospective, open-label, longitudinal study (NCT07052214) will enroll 204 male 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 conventional imaging.

All patients will undergo ^{68}Ga-PSMA-11 and MRI scans, followed by standard anatomical template biopsy (minimum 2 core in 6 sectors). PSMA and MRI scans will be independently interpreted by 3 blinded, qualified readers. MRI- and 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 6-months for patients with no baseline imaging or histopathological evidence of PCa. Additional imaging, template and/or targeted biopsies may be performed during the follow-up period, at the discretion of the investigator. Any additional biopsy, imaging, clinical, histological, genetic, and intervention data will contribute to the determination of the standard of truth. Follow-up will provide longitudinal surveillance to ensure that participants initially evaluated as negative for PCa on both imaging and histopathology are reliably negative.

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

Results: This study is open, with enrollment commencing this year.

Conclusions: PSMA PET combined with MRI for targeted biopsy 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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