Fully Hybrid 18F-PSMA PET/MRI as One-stop Approach for the Diagnosis of Clinically Significant Prostate Cancer.

NCT06305390

Status	RECRUITING
Phase	Phase 2
Sponsor	IRCCS San Raffaele
Enrollment	167 participants

Plain Language Summary

This study tests whether a combined PET/MRI scan using a special prostate-targeting tracer (18F-PSMA) can detect clinically significant prostate cancer better or more conveniently than separate imaging tests and biopsies done over multiple visits.

You may be eligible if...
- You are a man aged 18 or older
- Your doctor suspects you may have prostate cancer and has recommended a biopsy
- You are physically able to undergo all the procedures in the study
- You can provide written informed consent

You may NOT be eligible if...
- You have already been diagnosed with prostate cancer
- You cannot have an MRI scan (for example due to claustrophobia, a pacemaker, or reduced kidney function)
- You have a contraindication to prostate biopsy

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (3)

- Men at least 18 years of age referred with clinical suspicion of prostate cancer candidate for prostate biopsy
- Feasibility to undergo all procedures listed in protocol
- Ability to provide written informed consent

Exclusion (3)

- Prior diagnosis of prostate cancer
- Contraindication to MRI (e.g. claustrophobia, pacemaker, estimated GFR lower or equal to 50mls/min)
- Contraindication to prostate biopsy

Locations (1 total)

U.O. of Nuclear Medicine, ,Ospedale San Raffaele, Milan, Milano, Italy