

Title

Safety of [⁶⁸Ga]Ga-PSMA-11 prepared with the cold kit used in the Pivotal Lu-PSMA 617 Vision trial for selection of PSMA positive patients.

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Introduction and overall goal

An International, Prospective, Open-label, Multicenter, Randomized Phase 3 Study in the Treatment of Patients with Progressive PSMA-positive Metastatic Castration-resistant PC (mCRPC), named VISION, has been carried out. The eligibility of the patients in VISION was based on assessing the positive expression of PSMA detected via [⁶⁸Ga]Ga-PSMA-11 using an investigational “cold kit”.

Specific aims

Assessing the safety of [⁶⁸Ga]Ga-PSMA-11 as a companion diagnostic eligibility for patients who had PSMA-positive metastatic castration-resistant prostate cancer, which was defined as at least one PSMA-positive metastatic lesion and no PSMA-negative lesions that would be excluded according to the protocol criteria (Sartor et al.)

Rationale and background

Theranostics is an emerging field of targeted medicine with drugs uniquely combined to sequentially diagnose and treat disease.

Methods and materials

We here report the safety data from the use of [⁶⁸Ga]Ga-PSMA-11 in the VISION trial (NCT03511664). PSMA- positive status was determined with the use of centrally read [⁶⁸Ga]Ga-PSMA-11 using an investigational “cold kit”.

Results

Only 5 out of 206 subjects reported events considered possibly or probably related to [⁶⁸Ga]Ga-PSMA-11 . All were non-serious: General Disorders and Administration Site Conditions n=2 (Asthenia, Injection site warmth); Gastrointestinal disorders n= 1 (constipation); Vascular disorder n= 1 (Hot flush) and Nervous system disorder n=1 (cognitive disorder).

Discussion and conclusion

The safety results from this study are in agreement with literature reports where [⁶⁸Ga]Ga-PSMA-11 was used to assess PSMA status of lesions in patients with newly diagnosed PC or BCR . [⁶⁸Ga]Ga-PSMA-11 can be safely used to accurately detect and localize PSMA positive lesions in patients with prostate cancer and determine patients suitable for PSMA directed therapy.

References

Sartor O, de Bono J, Chi KN, et al. Lutetium-177-PSMA-617 for metastatic castration-resistant prostate cancer. *New England Journal of Medicine* 2021. doi: 10.1056/NEJMoa2107322