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Final results from a randomized phase II study of cabazitaxel (CBZ) versus an androgen receptor targeted agent (ARTA) in patients with poor-prognosis castration-resistant prostate cancer (mCRPC)

K. van der Zande[1], V. van der Noort[2], M. Busard[3], P. Hamberg[4], S. Ras - van Spijk[4], J. de Feijter[1], V. Dezentje[1], M. Tascilar[5], D. Houtsma[6], A. Beeker[7], P. van den Berg[8], D. ten Oever[9], I.M. Oving[10], W. Zwart[11], A.M. Bergman[1]

[1] Medical Oncology, NKI-AVL - Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital, Amsterdam, Netherlands, [2] Department of Biometrics, NKI-AVL - Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital, Amsterdam, Netherlands, [3] Department of Radiology, NKI-AVL - Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital, Amsterdam, Netherlands, [4] Medical Oncology, Franciscus Gasthuis & Vlietland, Schiedam, Netherlands, [5] Medical Oncology Department, Isala Hospital, Zwolle, Netherlands, [6] Internal medicine/medical oncology, HagaZiekenhuis locatie Leyweg, Den Haag, Netherlands, [7] Internal Medicine Department, Spaarne Ziekenhuis, Hoofddorp, Netherlands, [8] Medical Oncology Department, Tergooi Hospital, Hilversum, Netherlands, [9] Medical Oncology, Noordwest Ziekenhuisgroep - Alkmaar, Alkmaar, Netherlands, [10] Internal Medicine Department, Ziekenhuisgroep Twente (ZGT), Almelo, Netherlands[11] Oncogenomics, Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital (NKI-AVL), Amsterdam, Netherlands

Background

In the multicenter, phase IIb OSTRICH trial, poor-prognosis mCRPC patients were randomized between CBZ and ARTA, directly following progression on docetaxel (DOC) treatment.

Methods

mCRPC patients with poor-prognosis (≥1 factor: visceral metastases, CRPC within 1 year, progression ≤6 months after DOC completion) were randomized 1:1 between CBZ and ARTA (Abiraterone OR Enzalutamide). Primary endpoint was to establish the Clinical Benefit Rate (no radiotherapy, no ECOG PS increase ≥2, no therapy switch and no radiological progression) at 12 weeks (CBR) in both study arms, while comparison of the CBR was a secondary endpoint. A Fisher Exact test was used to assess differences in rates and a log rank test to assess differences in time to event endpoints.

Results

A total of 106 patients were randomized, 53 in each arm. Baseline median age was 70 and PSA 76 ng/ml. DOC was received in the HSPC stage in 36 patients (34%), while 40 patients (38%) received ARTA prior to DOC. CBR was 60.8% (95% CI: 46.1 – 74.2%) in the CBZ arm and 67.3% (95% CI: 52.9 – 79.7%) in ARTA arm (p=0.54)). At 12 weeks, PSA responses were 17% (95% CI: 8.1–29.8%) and 5.3% (95% CI:31.6–59.6%) in the CBZ and ARTA arms, respectively (p = 0.003). After a median follow-up of 30.9 (95% CI: 25 – NA) months, median Time to Symptomatic Progression was 4.2 (95% CI: 3.7 – 5.9) vs 5.8 (95% CI: 4.6 – 6.5) months in the CBZ vs ARTA arm (p=0.07). Time to Radiological progression was 7.1 (95% CI: 5.3 – 13.8) and 5.8 (95% CI: 5.4 – 11.4) months in CBZ and ARTA (p=0.77), Time to PSA progression was 3.6 (95% CI: 2.6 – 7.8) and 4.1 (95% CI: 3.3 – 8.9) months in the CBZ and ARTA arm (p=0.95), respectively. Progression free survival 2.5 (95% CI: 2.2 – 3.4) in the CBZ arm and 3 (95% CI: 2.6 – 3.6) months ARTA arm (p=0.24). Overall Survival was 14.9 (95% CI: 9.7 – 19.5) months in CBZ and 13.9 (95% CI: 11.7 – 16.5) months in the ARTA arm (p=0.53). Grade ≥3 adverse events (AEs) occurred in 62% and 26% patients in CBZ and ARTA arm.

Conclusions

No significant difference in CBR and time to event endpoints was established between CBZ and ARTA treated patients. Further studies will concentrate on prespecified subgroups.

Clinical trial identification

NCT03295565.

Legal entity responsible for the study

Dutch Uro-Oncology Studygroup.

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Disclosure

P. Hamberg: Financial Interests, Personal, Advisory Board: Astellas, MSD, Pfizer, AstraZeneca, BMS, Ipsen. J. de Feijter: Non-Financial Interests, Institutional, Advisory Role: Merck; Financial Interests, Institutional, Other, travel: Pfizer. V. Dezentje: Non-Financial Interests, Institutional, Advisory Role: Daiichi Sankyo. D. Houtsma: Non-Financial Interests, Institutional, Advisory Role: Pfizer, Amgen, Astellas. P. van den Berg: Non-Financial Interests, Advisory Role: Ipsen, Astellas, Bayer; Financial Interests, Invited Speaker: Janssen. W. Zwart: Financial Interests, Funding: Astellas. A.M. Bergman: Financial Interests, Institutional, Advisory Board: Astellas, Janssen, Bayer, Sanofi; Financial Interests, Institutional, Research Grant: Amgen, Astellas, Bayer, Sanofi; Other, Other, Financial support for attending conferences: Astellas, Sanofi, Bayer. All other authors have declared no conflicts of interest.

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