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Patient reported outcomes in resected renal cell carcinoma: Adjuvant durvalumab versus active monitoring in the RAMPART trial

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Background

RAMPART (NCT03288532) evaluates one year of adjuvant durvalumab for resected renal cell carcinoma at intermediate/high risk of relapse. Quality of life (QoL) assessment is essential to understand treatment impact. The primary QoL outcome (change in overall health and quality of life (OHQL) from baseline to Month 15) showed no evidence of a difference between durvalumab and active monitoring (AM). Here, we report detailed results.

Methods

Participants were randomly assigned (3:2) to AM or durvalumab, consented to the optional QoL study and completed the QLQ-C30 at baseline plus ≥1 follow-up (Week 16 or Month 15). Secondary QoL outcomes were OHQL at Week 16, and functioning, symptoms, and financial difficulties at Week 16 and Month 15. We predefined clinically meaningful difference (CMD) thresholds. Negative values in OHQL/functioning and positive values for symptoms indicate worse functioning with durvalumab.

Results

218 participants were included (131 AM, 87 durvalumab). Baseline characteristics were similar. At Week 16, durvalumab was associated with worse OHQL (–7.4 [small CMD 4 to <10]; 95% CI: –11.5 to –3.3; p = 0.0005), role function (–7.1 [small CMD 6 to <19]; 95% CI: –12.6 to –1.6; p = 0.0112), cognitive function (-5.3 [small CMD 3 to <9]; 95% CI: -9.6 to -0.9; p = 0.0174), fatigue (5.5; [small CMD 5 to <13] 95% CI: 0.7 to 10.2; p = 0.0239), and appetite loss (5.8 [small CMD 5 to <14]; 95% CI: 1.0 to 10.6; p = 0.0186). At Month 15, worsening persisted for cognitive function (-7.1; 95% CI: -12.7 to -1.5; p = 0.0135) and appetite loss (7.4; 95% CI 1.6 to 13.2; p = 0.0124), with new worsening in dyspnoea (7.5 [small CMD 4 to <9]; 95% CI: 0.6 to 14.5; p = 0.0341) and constipation (12.2 [small CMD 5 to <13]; 95% CI: 5.5 to 18.8; p = <0.0001). No other domains met both statistical and CMD thresholds at either timepoint.

Conclusions

Durvalumab was associated with early worsening in OHQL, role function, cognitive function, fatigue, and appetite loss. OHQL and role function improved by Month 15. Fatigue, cognitive function, and appetite loss remained worse, with later declines in dyspnoea and constipation. As dyspnoea and constipation are single-item scales with changes emerging only at Month 15, findings should be interpreted cautiously.

Clinical trial identification

NCT03288532.

Legal entity responsible for the study

University College London.

Funding

AstraZeneca.

Disclosure

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