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OP1 ADHERENCE TO 6-MONTH ORAL ALPHA LIPOIC ACID FOR PREVENTION OF PLATINUM-INDUCED POLYNEUROPATHY

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Background: Peripheral neuropathy induced by platinum-containing chemotherapy causes pain, and frequently becomes a dose-limiting factor for cancer treatment. The neurotoxicity appears to be irreversible; therefore prevention of neuropathy is necessary. Our aim was to determine whether α-lipoic acid (ALA, thioctic acid) can prevent peripheral neuropathy for patients receiving platinum.

Methods: Adult patients were randomised to receive either 600 mg ALA or placebo three times a day for 24 weeks. Neuropathy was measured by the FACT/GOG-NTX score, and pain was measured by the brief pain inventory (BPI).

Findings: Of the 243 patients randomised, 96 completed treatment for 24 weeks. At baseline, the ALA ($n = 122$) and placebo ($n = 121$) groups were comparable for age (58 ± 11 and 60 ± 11 years; $p = 0.26$), gender (51% and 49% male; $p = 0.85$), prior platinum exposure ($p > 0.99$), FACT/GOG-NTX score, and BPI score. At 24 weeks, only 43 evaluable patients remained in the ALA group, and 53 evaluable patients in the placebo group. The drop-out rate was 65% for the ALA group and 56% for placebo ($p = 0.17$). Reasons for drop-out were: withdrew consent (57 of 147, 39%), refused to take medication or non-compliant (35 of 147, 24%), lost to follow-up (2 of 147, 3%), death (2 of 147, 1%), change of chemotherapy regimen (8 of 147, 5%), physician decision (8 of 147, 5%), adverse effects (4 of 147, 3%), or other (31 of 147, 21%).

Interpretation: Intensive schedules of oral agents may be particularly challenging in the symptom-prevention setting. Strategies to gauge the pre-enrolment risk of non-adherence, and to monitor adherence, are worthy of further exploration.

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OP2 NAB-PACLITAXEL IN THE TREATMENT OF ADVANCED PANCREATIC CANCER REFRACTORY TO GEMCITABINE – FINAL RESULTS OF A PHASE 2 TRIAL

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Background: There are few treatment options for patients with advanced pancreatic cancer who do not respond to gemcitabine. Expression of secreted protein acidic and rich in cysteine (SPARC) might be a predictive marker of activity for nanoparticle albumin-bound (Nab)-paclitaxel (Nab-P). We aimed to assess the feasibility and efficacy of Nab-P in gemcitabine-refractory individuals, and the use of SPARC as a predictive factor.

Methods: In this phase 2 trial, patients with advanced pancreatic cancer refractory to gemcitabine and with ECOG performance status (PS) 0–2, received Nab-P 100 mg/m^2 on days 1, 8, and 15 of a 28-day cycle. The primary endpoint was 6-month overall survival (OS). Secondary endpoints were response rate (by RECIST criteria), progression-free survival (PFS), safety and toxicity profile, and SPARC expression.

Findings: 19 eligible patients accrued. The median age was 61 years, nine patients were male, 18 had stage IV disease, and 15 had a PS of 0–1. 6-month OS was 58% (95% CI 33–76%), median OS was 7.3 months (2.8–13.3), and median PFS was 1.6 months (1.5–3.4). One patient had a partial response (PR) and six had stable disease (SD; three of which lasted longer than 6 months). After two cycles, the median CA 19-9 level decreased by 52% in patients who had SD or PR, versus 18% in patients with PD. Non-haematological toxicities were generally mild, with grade 1 or 2 nausea in 63% of patients, anorexia in 47%, hypocalcaemia in 37%, and vomiting in 26%. Grade 3 or 4 neutropenia, neutropenic fever, and anaemia occurred in 32%, 11%, and 11% of patients, respectively. There were no cases of grade 3 or 4 neuropathy. SPARC expression did not correlate with clinical outcomes.

Interpretation: Nab-P is active in pancreatic cancer refractory to gemcitabine. A randomised phase 3 trial is ongoing to confirm the efficacy of Nab-P in pancreatic cancer, and the usefulness of SPARC as a predictor of its activity.

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