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1627TiP Impact of patient education on immune-related adverse events (irAEs) during immune checkpoint inhibitor (ICI)

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Background: ICI transformed the prognosis of incurable cancers with lasting remissions. Their original mechanism of action causes side effects related to the immune response (irAEs). Patient Education (PE) could optimize detection, management of irAEs and improve quality of life. The aim of this study is to compare Grade≥3 irAEs in a group of educated patients vs standard care group.

Trial design: A prospective randomised controlled multicentre trial testing an educative program on patients with ICI was approved by the Ethics Committee. The same educational intervention using common tools (REPERE kit) is used in the experimental group (N=274), independent of the centre, versus the control group (N=137). Randomisation 2:1 with minimization on center, location, age, autoimmune disease, ICI combination with ICI/RT/chemotherapy/TKI is applied. Population: patients with cancer (Non-Small Cell Lung Cancer, Renal Cell Cancer, bladder cancer, Head and Neck Cancer, melanoma, cutaneous Squamous Cell Carcinomaand any new FDA approval) treated with ICI are enrolled in the trial. IrAES are analysed by Gustave Roussy's Pharmacovigilance Unit and incremented in the REISAMIC database which is dedicated to the collection of immunotherapy severe adverse events (CTCAE Grade≥3). Since December 2019, 243 patients /411 were enrolled within 14 investigating centers. 238 patients were randomized, 158 in the experimental group and 80 in the control group.

Conclusions: Education of patients with ICI is essential to increase irAEs self-reporting in the current health context. This ongoing trial aims to empower the patient and enhance patient-clinician communication will assess the impact of PE during ICI treatment. Although it started in a pandemic context, this trial has gained the approval of patients and caregivers. Nowadays, with the increase in prescription of ICI for early stages of cancer, a surge in the number of patients is expected which necessitates implementing PE early on. This work was supported by a grant from the Nurse and paramedical Research Hospital Program from the French Ministry of Health PHRIP-18-0271.

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1628TiP Romiplostim for chemotherapy-induced thrombocytopenia (CIT) in solid tumors: Two phase III, international, randomized controlled trials (RCT)

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Background: CIT is a common and challenging complication of cancer therapy, resulting in chemotherapy dose reduction, treatment delay, and discontinuation. Platelet (Plt) transfusions provide only a transient benefit, are costly, associated with risk of adverse events, and have limited availability. Until recently, chemotherapy dose modifications and Plt transfusions were the only management options for CIT. NCCN guidelines now include consideration of the TPO receptor agonist romiplostim for CIT based on data from a phase 2 prospective randomized study and retrospective studies. We describe here two ongoing pivotal phase 3 RCT of romiplostim to treat CIT.

Trial design: Adult patients receive (trial 1) oxaliplatin-based chemotherapy for gastrointestinal, pancreatic, or colorectal cancer (NCT03362177) or (trial 2) carboplatin-based chemotherapy for non-small cell lung, ovarian, or breast cancer (NCT03937154). In each trial, 162 patients with Plt $\leq 85\times10^9$/L and CIT from a prior regimen will be randomized 2:1 to receive romiplostim or placebo, respectively, stratified by baseline Plt count and tumor type (trial 1) or specific carboplatin regimen (trial 2). After initiation of study drug at 2 μg/kg subcutaneously, patients will be dosed weekly, adjusting by 1 μg/kg to ≤10 μg/kg, to achieve Plt counts $\geq 100\times10^9$/L. Chemotherapy can start when Plt counts are $>100\times10^9$/L or Week 4 per investigator; after 12 weeks, those not achieving Plt counts $\geq 100\times10^9$/L, or a Plt count deemed safe to proceed with chemotherapy, stop treatment and enter follow-up. Interim analyses for each trial will occur when 81 patients have completed 3 chemotherapy cycles. The primary endpoint for both studies is thrombocytopenia-induced dose modification of any myelosuppressive agent in the second and third cycles of the planned chemotherapy regimen (ie, dose reduction, delay, omission, or discontinuation) as adjudicated by an independent committee (oncologists and a biostatistician). Secondary endpoints include depth of the Plt nadir, time to Plt response, duration-adjusted rate of grade ≥2 bleeding, overall survival, Plt transfusion incidence, proportion achieving a Plt response, and safety.

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