The aim of this phase II clinical trial was to evaluate the preventive effect of dexamethasone mixing injection for venous pain in patients with colorectal cancer during chemotherapy" Hata et al (2015).

Abstract:

PURPOSE: The aim of this phase II clinical trial was to evaluate the preventive effect of dexamethasone mixing injection for venous pain in patients with colorectal cancer during chemotherapy.

MATERIALS AND METHODS: Patients were randomized to receive a 2-h intravenous infusion of oxaliplatin 130 mg/m(2) on day 1 followed by capecitabine 1000 mg/m(2) (or S-1 40-60 mg/m(2)) twice daily on days 1 through 14 of every 3 weeks with or without dexamethasone 1.65 mg at the infusion on day 1.

RESULTS: A total of 53 patients were enrolled. The analysis population consisted of 49 patients (arm A, with dexamethasone N = 24; arm B, without dexamethasone N = 25). The incidence of venous pain ≥grade 2 based on the CTCAE version 4.0 was 33.3 % in arm A and 56.0 % in arm B (relative risk 0.60; 95 % CI 0.31-1.16). The incidences based on the verbal rating scale for arms A and B were 50.0 and 64.0 %, respectively (relative risk 0.78; 95 % CI 0.48-1.28).

CONCLUSION: The primary endpoint was not met in this preliminary study.

Reference:

Hata, T., Honda, M., Kobayashi, M., Toyokawa, A., Tsuda, M., Tokunaga, Y., Takase, K., Miyake, M., Morita, S., Nagata, N., Sakamoto, J., Gosho, M. and Mishima, H. (2015) Effect of pH adjustment by mixing steroid for venous pain in colorectal cancer patients receiving oxaliplatin through peripheral vein: a multicenter randomized phase II study (APOLLO).

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