

Supplemental Appendix for:

Ramosetron Versus Ondansetron in Combination with Aprepitant and Dexamethasone for the Prevention of Highly Emetogenic Chemotherapy-induced Nausea and Vomiting: A Multicenter, Randomized Phase III Trial, KCSG PC10-21
Jin-Hyoung Kang et al.

Appendix S1. Criteria for participant inclusion or exclusion

Inclusion Criteria:

1. Age > 19 years and a diagnosis of a malignancy that can be treated with highly emetogenic chemotherapeutic agents (NCCN guideline v1.0 2011 anti-emesis).
2. ECOG performance status of 0–2.
3. Ability to receive orally administered study drugs.
4. Submission of informed consent for indicating an awareness of the investigational nature of the study in keeping with the policy of the hospital.

Exclusion Criteria:

1. Severe hypertension, severe heart disease, kidney disease (serum creatinine > 3 mg/dL), or liver disease (AST or ALT level > 3 times the upper normal range, ALP level > 2 times the upper normal range).
2. GI obstruction, active gastric ulcer, or other diseases that could cause nausea and vomiting.
3. Nausea and vomiting during the week before chemotherapy.
4. Use of steroids, antiemetics, pimozide, terfenadine, astemizole, cisapride, rifampin, carbamazepine, phenytoin, ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir, or nelfinavir for the treatment of other diseases.
5. A brain tumor, brain metastasis, or seizure.
6. Chemotherapy treatment within 12 months before enrollment.
7. A need for radiation therapy during the study period or treatment with radiation therapy within 2 weeks before chemotherapy.
8. Development of known allergies or severe side effects in response to drugs used in this study.
9. Pregnant or lactating women, or women who wish to become pregnant.
10. Patients judged inappropriate as subjects for this study by the investigator.