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Personalizing antiemetic prophylaxis for patients at high emetic risk: Results from the MyRisk Trial

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Background

Patients receiving moderately emetogenic chemotherapy (MEC) are commonly prescribed a 5-HT3 receptor antagonist (RA) and dexamethasone (DEX) as standard of care (SOC) antiemetic prophylaxis. However, in patients with an elevated emetic risk due to personal risk factors, prophylaxis consistent with highly emetogenic chemotherapy may be warranted. To address this unmet need for a more personalized antiemetic strategy, the MyRisk trial incorporated a previously validated predictive risk factor algorithm to select patients at increased risk of chemotherapy-induced nausea and vomiting (CINV) who may benefit from the addition of an NK₁RA.

Methods

MyRisk was a phase IV, randomized, open-label, multicenter, multinational trial (NCT04817189). Adult patients scheduled to receive 3 cycles of MEC with a high risk score were randomized to NEPA (a fixed combination of an NK₁RA, netupitant, and 5-HT₃RA, palonosetron) + DEX or SOC. The primary endpoint was complete response (no emesis/no rescue) during the overall (0-120h) phase over 3 consecutive cycles. The analysis used a generalized linear model with logit link function, binomial distribution, generalized estimating equations and with "study treatment", "carboplatin use" and "country" as covariates. Secondary endpoints of complete protection, no emesis, no nausea, and no rescue medication were analyzed similarly.

Results

A total of 388 patients (55% male) were included. The most common cancers were colorectal (42%) and lung (19%); oxaliplatin (64%) and carboplatin (30%) were the most common MEC. NEPA was superior to SOC in all efficacy endpoints except for rescue use. Table: 28010

Response Endpoint Over 3 Cycles of MEC	NEPA(n =	189) SOC $(n = 1)$	99) Odds R	atio 95% CI	p-value
Complete response (no emesis, no rescue)	81.0%	71.8%	1.67	1.12 to 2.	490.012
Complete protection (no emesis, no rescue, no nausea)	71.8%	62.4%	1.53	1.06 to 2.	21 0.022
No emesis	95.4%	86.7%	3.18	1.62 to 6.	22<0.001
No nausea	63.7%	54.9%	1.45	1.01 to 2.	060.042
No rescue medication	82.4%	76.5%	1.43	0.94 to 2.	180.091

Conclusions

This novel trial integrating pre-treatment individual risk factors with planned MEC found NEPA to be superior to SOC in preventing CINV in patients at increased emetic risk, highlighting the benefit of a personalized approach to antiemetic prophylaxis. Risk factor evaluation

should be considered for all patients receiving MEC to optimize CINV control.

Clinical trial identification

NCT04817189.

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Legal entity responsible for the study

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Disclosure

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