Plus or Minus Olanzapine in the Prevention of Chemotherapy-Induced Nausea and Vomiting?

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<tr>
<th>Section</th>
<th>Pages</th>
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<tr>
<td>Systematic Review: Sutherland A, et al.</td>
<td>5 - 9</td>
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### Summary of CINV Treatment Guidelines

<table>
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<tr>
<th>Acute</th>
<th>Delayed</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-HT3</td>
<td>DEX</td>
</tr>
<tr>
<td>NK1</td>
<td>OLZ</td>
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</tbody>
</table>

**Note:** If anthracycline and cyclophosphamide combo use olanzapine only

#### HEC ASCO 2017

**Acute**

<table>
<thead>
<tr>
<th>5-HT3</th>
<th>NK1</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEX</td>
<td>OLZ</td>
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</tbody>
</table>

**Delayed**

| DEX   | OLZ |

#### HEC MASCC/ESMO 2019

**Acute**

<table>
<thead>
<tr>
<th>5-HT3</th>
<th>NK1</th>
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<tbody>
<tr>
<td>DEX</td>
<td></td>
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<tr>
<td>± OLZ</td>
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**Delayed**

If non-AC:

<table>
<thead>
<tr>
<th>MCP</th>
<th>DEX</th>
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</table>

or

| APR   | DEX |

± OLZ

If AC:

NONE

#### HEC NCCN 2019

**Acute**

<table>
<thead>
<tr>
<th>5-HT3</th>
<th>NK1</th>
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<tbody>
<tr>
<td>DEX</td>
<td>OLZ</td>
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</tbody>
</table>

or

| PAL   | OLZ |

| DEX   |

or

| APR   |

| DEX   |

| APR   |

| DEX   |

**Delayed**

| APR   | OLZ |

| DEX   |

or

| OLZ   |

| DEX   |

| APR   |

| DEX   |

| APR   |

**Note:** Order does not imply preference.
<table>
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<th>MEC MASCC/ESMO 2019</th>
<th>MEC NCCN 2019</th>
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<tr>
<td><strong>Acute</strong></td>
<td><strong>Acute</strong></td>
<td><strong>Acute</strong></td>
</tr>
<tr>
<td>5-HT3</td>
<td>5-HT3</td>
<td>5-HT3</td>
</tr>
<tr>
<td>DEX</td>
<td>DEX</td>
<td>DEX</td>
</tr>
</tbody>
</table>

If carboplatin AUC ≥ 4 mg/mL/min:

- **Acute**
  - 5-HT3
  - NK1
  - DEX

Note: With agents known to cause delayed N/V DEX may be added to days 2-3

<table>
<thead>
<tr>
<th></th>
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<tr>
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<td><strong>Delayed</strong></td>
<td></td>
</tr>
<tr>
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<td></td>
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</tr>
</tbody>
</table>

If carboplatin:

- **Delayed**
  - NONE
  - APR

If oxaliplatin, anthracycline, or cyclophosphamide:

- **Delayed**
  - 5-HT3
  - DEX

*Order does not imply preference*
## Olanzapine for the prevention and treatment of cancer-related nausea and vomiting in adults


<table>
<thead>
<tr>
<th>Design</th>
<th>Included randomized, blinded or unblinded, parallel-arm, single or multi-centered controlled trials</th>
</tr>
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<tbody>
<tr>
<td>Objective</td>
<td>To assess the efficacy and safety of olanzapine when used as an antiemetic in the prevention and treatment of nausea and vomiting related to cancer in adults</td>
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### Search Methods
- CENTRAL, MEDLINE and EMBASE for published data on September 20, 2017
- ClinicalTrials.gov
- World Health
- Organization International Clinical Trials Registry Platform
- Experts in the field and study authors

### Inclusion Criteria
- **Types of studies**
  - RCTs
  - Open-label studies
  - Minimum of 10 participants per treatment arm
- **Types of participants**
  - High-, middle-, and low-income countries
  - Inpatients or outpatients with any stage or type of cancer
  - Participants 18 years or older treated with olanzapine to prevent nausea and vomiting

### Exclusion Criteria
- **Types of studies**
  - Quasi-randomized trials
  - Non-randomized studies, case series, case reports, and observational studies
  - Short abstracts unless additional information was provided
  - Studies without results
- **Types of participants**
  - Olanzapine used in non-cancer patients
  - Pediatric participants

### Standard Treatment Regimens
- A 5-HT3 receptor antagonist
- A 5-HT3 antagonist and an NK-1 receptor antagonist
- Dexamethasone and a 5-HT3 receptor antagonist
- Dexamethasone, an NK-1 receptor antagonist, and a 5-HT3 receptor antagonist
- Dexamethasone, an antihistamine, and a 5-HT3 antagonist
- 1 trial (Nikbakhsh 2016) did not state the standard regimen used
- 1 trial (Navari 2010) used participants not receiving chemotherapy or radiotherapy, but receiving olanzapine and megestrol or megestrol alone and therefore was not included in the meta-analysis

### Interventions
- **Comparison pairs**
  - 9 studies compared olanzapine to placebo or no treatment
  - 4 studies compared olanzapine to other antiemetics
    - NK-1 receptor antagonists
    - 5-HT3 receptor antagonists
    - Prokinetics
    - Steroids
  - All participants had treatment in conjunction with other medications, mainly antiemetics
- Oral olanzapine: tablet, solution, orally-disintegrating ‘wafer’ or ‘velotab,’ or custom black gel capsule for blinding purposes
- **Dosing**
  - 8 trials: 10 mg daily (as single dose or in divided doses of 5 mg BID)
  - 4 trials: 5 mg daily (as single dose or in divided doses of 2.5 mg BID)
  - 1 trial: range of 2.5-10 mg dependent upon patient tolerance
  - 1 trial: 2.5 mg daily and could not be included in meta-analysis

### Endpoints
- **Primary outcomes**
  - The proportion of participants w/o nausea or vomiting over the time period studied
  - Serious adverse events
    - Extra pyramidal events
    - QTc prolongation
    - Neutropenia
    - Agranulocytosis
- **Secondary outcomes**
  - Patient perception of treatment including:
    - Patient preference (as a dichotomous yes/no outcome)
    - Validated quality-of-life measures
  - Other adverse events, as measured by the proportion of participants experiencing at least one of these
  - Somnolence and fatigue, as measured by the proportion of participants experiencing at least one of these

### Statistical Analysis
- **Risk of bias**
  - Allocation concealment
  - Blinding of participants and outcome assessment
  - Reporting bias
Incomplete outcome data
Size of studies

- Measures of treatment effect
  - Dichotomous outcomes: RR, with 95% CI
    - Data presented using OR for truer reflection of heterogeneity
  - Continuous data: treatment effects expressed as mean, with standard deviation, or as standardized mean difference

- NNTB and NNTH
- Intention-to-treat
- Heterogeneity
  - Forest plots and heterogeneity statistics
- GRADE to rate quality
- Subgroup analysis
  - The effect dose of 2.5 mg versus 5 mg versus 10 mg BID
  - Clinical setting: chemotherapy, radiotherapy, or no active oncology treatment
  - Efficacy of olanzapine in MEC versus HEC
- Sensitivity analysis to determine robustness
  - Fixed-effect versus random effects
  - Risk of bias of included studies
  - Methods of outcome measurement

Results

- Enrollment: n=14 RCTs (1917 participants)
  - 13 included in meta-analysis
  - 20 studies excluded
    - 3 were not considered RCTs
    - 2 used wrong intervention
    - 4 included pediatric patients
    - 4 studies terminated early
    - 5 studies used wrong comparison
    - 2 used olanzapine for wrong indication

- Population:
  - Males and females ages 18-81 years
  - Solid and hematological malignancies
  - Participants receiving chemotherapy with or w/o radiotherapy
  - 1 study included participants receiving hematopoietic stem cell transplantation
  - 1 study included participants who were not receiving chemotherapy nor radiotherapy, but received olanzapine with megestrol or megestrol alone
<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Relative effect (95% CI)</th>
<th>Anticipated absolute effects* (95% CI)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>No olanzapine</td>
</tr>
<tr>
<td>No N/V over trial period</td>
<td>RR 1.98 (1.59 to 2.47)</td>
<td>Study population: 561 participants (3 RCTs)</td>
</tr>
<tr>
<td></td>
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<td>25.1%</td>
</tr>
<tr>
<td>Serious adverse events</td>
<td>RR 2.46 (0.48 to 12.55)</td>
<td>Study population: 889 participants (7 RCTs)</td>
</tr>
<tr>
<td></td>
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<td>0.5%</td>
</tr>
<tr>
<td>Participant preference - wish to use drug in next treatment</td>
<td>RR 1.43 (0.97 to 2.09)</td>
<td>Study population: 48 participants (1 RCT)</td>
</tr>
<tr>
<td></td>
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<td>58.3%</td>
</tr>
<tr>
<td>Quality of life</td>
<td></td>
<td>Study population: 258 participants (4 RCTs)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mizukami 2014: Olanzapine group-better QOL per Functional Living Index-Emesis questionnaire (P &lt; 0.0004)</td>
</tr>
<tr>
<td></td>
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<td>Mukhopadhyay 2016: Global health status improved in the olanzapine group using the EORTC QLQ C30 (before 9.48 ± 0.48 and after treatment 9.60 ± 0.47; P = 0.537) unlike the control group</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Navari 2010b: 23/39 participants in the megestrol + olanzapine group had improved QOL at 4 &amp; 8 weeks compared to 5/37 in the megestrol only group on the Functional Assessment of Cancer Therapy-General</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nikbakhsh 2016: No difference in total QOL score (P &gt; 0.05) using the WHO-QOL-BREF</td>
</tr>
<tr>
<td><strong>Other adverse events</strong></td>
<td>RR 1.71 (0.99 to 2.96)</td>
<td>Study population: 332 participants (4 RCTs)</td>
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<tr>
<td>--------------------------</td>
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<td></td>
<td></td>
<td>8.4%</td>
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<tr>
<td></td>
<td></td>
<td>14.4%</td>
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<td></td>
<td></td>
<td>6.0% more (0.1 fewer to 16.5 more)</td>
</tr>
<tr>
<td><strong>Somnolence/fatigue</strong></td>
<td>RR 2.33 (1.30 to 4.18)</td>
<td>Study population: 464 participants (5 RCTs)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>13.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8.2% more (1.9 more to 18.8 more)</td>
</tr>
</tbody>
</table>

**Authors’ Conclusions**

**No N/V over trial period:** Olanzapine probably improves freedom from N/V over the trial period when compared to placebo or no intervention when used with standard therapy (OR 5.48, 95% CI 1.35 to 22.20, I² = 85%) - GRADE Moderate

**Serious adverse events:** It is unknown if olanzapine increases the risk of serious adverse events when used with standard therapy. Six RCTs reported no serious adverse events in either arm (OR 2.50, 95% CI 0.48 to 13.04; I² = 0%) - GRADE Low

**Participant preference - wish to use drug in next treatment:** It is unknown if participants preferred olanzapine when compared to placebo or no intervention when used with standard therapy (OR 3.57, 95% CI 0.93 to 13.72) - GRADE Moderate

**Quality of life:** It is unknown whether participants who used olanzapine had an improved quality of life compared to placebo or no intervention, when standard therapy was used due to inter-study heterogeneity in scales used

**Other adverse events:** Olanzapine may lead to more adverse events when compared to placebo or no treatment if used with standard therapy (OR 2.05, 95% CI 0.99 to 4.22; I² = 0%)

**Somnolence/fatigue:** Olanzapine probably leads to increased risk of somnolence or fatigue when compared to placebo or no intervention when used with standard therapy (OR 2.84, 95% CI 1.39 to 5.78; I² = 0%)
| Olanzapine for the prevention of chemotherapy-induced nausea and vomiting<sup>28</sup>  
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Design</strong></td>
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</table>
| **Objectives** | **Primary**  
- To evaluate olanzapine versus placebo in the control of nausea in participants receiving HEC, with nausea prevention assessed during three periods:  
  - 0-24 hours  
  - 25-120 hours  
  - 0-120 hours after chemotherapy  
**Secondary**  
- To evaluate the number of patients with a complete response  
- To evaluate potential toxic effects of olanzapine |
| **Inclusion Criteria** |  
- ≥ 18 years of age  
- Malignant disease without history of chemotherapy  
- Cisplatin ≥ 70 mg/m<sup>2</sup> or Doxorubicin dose of 60 mg/m<sup>2</sup> + Cyclophosphamide 600 mg/m<sup>2</sup>  
- European Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2  
- For women of childbearing age, negative pregnancy test within 7 days of enrollment |
| **Exclusion Criteria** |  
- Serum creatinine > 2 mg/dL  
- AST or ALT > 3 x upper limit of normal  
- ANC> 1500 m<sup>3</sup>  
- Pregnant  
- Nausea/vomiting within 24 hrs. of enrollment  
- Severe cognitive impairment  
- CNS disease  
- Antipsychotic agents within 3o days of enrollment  
- Long-term phenothiazine use  
- Amifostine and quinolone use  
- Abdominal radiotherapy  
- Uncontrolled HF, DM, or MI within 6 months of enrollment  
- Hypersensitivity to olanzapine |
| **Intervention** | Day 1: 5-HT3 + NK1  
Days 1-4: DEX + OLZ or placebo |
| **Assessment** | **Pre-study Period**  
- Demographics  
- Medical data  
**Study Period**  
- Participants logged episodes of vomiting or retching daily and the use of rescue therapy during days 1-5 of chemotherapy and daily levels of nausea using visual-analogue scales |
Every 5 days participants rated undesired sedation and undesired increase in appetite using a numerical scale  
Nurses contacted patients to record adverse effects and assessed adherence to logs  

Endpoints  
Primary endpoint  
No nausea  
  - Early: 0-24 hours  
  - Later: 25-120 hours  
  - Overall: 0-120 hours after chemotherapy  
Secondary endpoint  
Complete response  
  - No emetic episodes  
  - No use of rescue medication  

Statistical Analysis  
- 332 patients (166 per group) required to provide power of 0.90  
- Interim analysis  
- Pearson’s chi-square tests to compare the proportion of patients with no nausea between treatment groups  
- Logistics models used for patient characteristics  
- Modified intention-to-treat  

Results  
Baseline Characteristics  
- 380 patients enrolled  
  - 192 - olanzapine  
  - 188 - placebo  
  - Median age: 57  
  - Female: n=275 (72.4%)  
  - Doxorubicin + cyclophosphamide: 244 (64.2%)  

Primary Endpoint: Efficacy  

<table>
<thead>
<tr>
<th></th>
<th>Olanzapine (N=192)</th>
<th>Placebo (N=188)</th>
<th>Total (N=380)</th>
<th>P Value</th>
<th>Adjusted P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-24 hours after chemotherapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No nausea</td>
<td>135/183 (73.8)</td>
<td>82/181 (45.3)</td>
<td>217/364 (59.6)</td>
<td>&lt;0.001</td>
<td>0.002</td>
</tr>
<tr>
<td>25-120 hours after chemotherapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No nausea</td>
<td>75/177 (42.4)</td>
<td>45/177 (25.4)</td>
<td>120/354 (33.9)</td>
<td>0.001</td>
<td>0.002</td>
</tr>
<tr>
<td>0-120 hours after chemotherapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No nausea</td>
<td>66/177 (37.3)</td>
<td>39/178 (21.9)</td>
<td>105/355 (29.6)</td>
<td>0.002</td>
<td>0.002</td>
</tr>
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</table>
### Secondary Endpoint: Efficacy

<table>
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<tr>
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<th>Olanzapine (N=192)</th>
<th>Placebo (N=188)</th>
<th>Total (N=380)</th>
<th>OR</th>
<th>P Value</th>
<th>Adjusted P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number/total number (percent)</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>0-24 hours after chemotherapy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete response</td>
<td>156/182 (85.7)</td>
<td>117/181 (64.6)</td>
<td>273/363 (75.2)</td>
<td>0.30</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>25-120 hours after chemotherapy</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete response</td>
<td>109/163 (66.9)</td>
<td>88/168 (52.4)</td>
<td>197/331 (59.5)</td>
<td>0.55</td>
<td>0.007</td>
<td>0.007</td>
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<tr>
<td><strong>0-120 hours after chemotherapy</strong></td>
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</tr>
<tr>
<td>Complete response</td>
<td>103/162 (63.6)</td>
<td>69/170 (40.6)</td>
<td>172/332 (51.8)</td>
<td>0.39</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Adverse Events**

- **Grade 3**
  - Olanzapine group: fatigue, hyperglycemia
  - Placebo group: abdominal pain, diarrhea
- **Grade 4**
  - Olanzapine group: hematologic
  - Placebo group: none
- Sedation significantly increased in olanzapine group when compared to placebo group
- No differences between groups when undesired increase in appetite was evaluated

**Authors’ Conclusions**

- Olanzapine combined with a 5HT-3 receptor antagonist, an NK-1 receptor antagonist, and dexamethasone is more effective than placebo combined with the same agents for the prevention of nausea and vomiting in patients who are chemotherapy naïve receiving HEC
- Studies utilizing multiple chemotherapy cycles are needed
- The dosing of olanzapine should be further explored
- More detailed information needed regarding the drowsiness seen with olanzapine
Appendix A: Navari RM, et al. Figures

![Diagram](image1)

A Undesired Sedation

<table>
<thead>
<tr>
<th>Day</th>
<th>Baseline</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
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<td>Mean Score</td>
<td>Olanzapine</td>
<td>Placebo</td>
<td>Olanzapine</td>
<td>Placebo</td>
<td>Olanzapine</td>
<td>Placebo</td>
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<tr>
<td>0</td>
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No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>Olanzapine</th>
<th>Placebo</th>
</tr>
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<tbody>
<tr>
<td>190</td>
<td>188</td>
<td></td>
</tr>
<tr>
<td>181</td>
<td>181</td>
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<tr>
<td>175</td>
<td>174</td>
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</tr>
</tbody>
</table>
B Undesired Increase in Appetite

No. at Risk
Olanzapine  190  183  182  179  179  176
Placebo     187  181  180  179  174  174
Appendix B: Yanai T, et al. Figures

![Graph 1: Probability of treatment success over time from cisplatin administration for 10mg and 5mg doses.](image1)

![Graph 2: Estimated change from baseline in the VAS for somnolence over time from cisplatin administration for 10mg and 5mg doses.](image2)
Appendix C: Abbreviations

AC: Cyclophosphamide and doxorubicin regimen
ALT: Alanine transaminase
ANC: Absolute neutrophil count
APR: Aprepitant
AR: Absolute risk
ASCO: American Society of Clinical Oncology
AST: Aspartate aminotransferase
AUC: Area under the curve
BID: Twice a day
BP: Blood pressure
CENTRAL: Cochrane Central Register of Controlled Trials
CHEMO: Chemotherapy
CI: Confidence interval
CINV: Chemotherapy-induced nausea and vomiting
CNS: Central nervous system
DEX: Dexamethasone
DOP: Dopamine
ECOG: Eastern Cooperative Oncology Group
EORTC QLQ-C30: European Organization for Research and Treatment of Cancer quality of life questionnaire
GI: Gastrointestinal
HEC: Highly emetogenic chemotherapy
HF: Heart failure
HLD: Hyperlipidemia
HT: Height
HTN: Hypertension
I²: Heterogeneity
MASCC/ESMO: Multinational Association of Supportive Care in Cancer/European Society for Medical Oncology
MCP: Metoclopramide
MEC: Moderately emetogenic chemotherapy
MI: Myocardial infarction
NCCN: National Comprehensive Cancer Network
NK1: Neurokinin-1 receptor antagonist
NNTB: Number needed to treat for an additional beneficial outcome
NNTH: Number needed to treat for an additional harmful outcome
NSCLC: Non-small cell lung cancer
N/V: Nausea and vomiting
OLZ: Olanzapine
OR: Odds ratio
P: Pulse
PAL: Palonosetron
PMH: Past medical history
QOL: Quality of life
QTc: corrected Q-T
RCT: Randomized controlled trial
R: Respiratory rate
RR: Risk ratio
T: Temperature
WHO-QOL-BREF: World Health Organization Quality of Life-BREF
w/o: without
WT: Weight
5-HT3: Serotonin receptor antagonist
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