Respiratory Outcomes from a Phase 1, Placebo-controlled Trial to Compare the Effects of Buprenorphine Buccal Film and Oral Oxycodeone Hydrochloride

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Introduction

Background
- Respiratory depression is the leading cause of death due to opioid overdose
- A similar model was used to assess the difference between each treatment and placebo at each post

Methods

Assessments
- Ventilatory response was measured by hypoventilation through assessment of the maximum decrease in minute ventilation (E_{\text{max}})
- This partial agonism at the µ opioid receptor contributes to the efficacy of buprenorphine agonists
- This partial agonism at the µ opioid receptor together with antagonism at the α2-adrenergic and norepinephrine

Subjects
- Subjects were healthy adult men and women who self

Results

Table 1. Subject Demographics and Depositions

<table>
<thead>
<tr>
<th>Category</th>
<th>Subjects, n=30</th>
<th>Complete (n=25)</th>
<th>Partial Completers (n=5)</th>
<th>Completers (n=18)</th>
<th>Partial Completers (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>33.1 (4.5)</td>
<td>32.8 (4.3)</td>
<td>33.1 (4.5)</td>
<td>32.8 (4.3)</td>
<td>32.8 (4.3)</td>
</tr>
<tr>
<td>Gender, male/female</td>
<td>25/5</td>
<td>21/4</td>
<td>25/5</td>
<td>21/5</td>
<td>21/5</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Asian</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>White</td>
<td>25</td>
<td>21</td>
<td>25</td>
<td>21</td>
<td>21</td>
</tr>
</tbody>
</table>

Results (cont’d)

Figure 4. Mean Minute Ventilation Over Time (Partial Completers, n=16)

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References

Author Disclosures

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