**Background**

- There are no established treatments for patients with AGC with progressive disease following or intolerant of ≥ 2 prior chemotherapy regimens (NCT02267343).

- Nivolumab is a fully human IgG4 monoclonal antibody that targets PD-1, with demonstrated activity in gastric cancer; however, efficacy has not been established in a randomized trial.

- Key eligibility criteria:
  - Histologically confirmed gastric adenocarcinoma or gastroesophageal junction adenocarcinoma.
  - Age ≥ 20 years.
  - ECOG PS 0–2.
  - Any prior therapy, with the exception of immunotherapy for AGC.
  - Measurable lesion.

- A total of 493 patients were randomized from 49 centers in 3 countries between November 2014 and May 2015

**Methods**

- A total of 493 patients were randomized from 49 centers in 3 countries between November 2014 and May 2015.

**Results**

### Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Nivolumab 3 mg/kg (N = 247)</th>
<th>Placebo (N = 246)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary site of disease</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stomach</td>
<td>123 (50.1)</td>
<td>123 (50.1)</td>
<td>1.00</td>
</tr>
<tr>
<td>Gastric</td>
<td>124 (50.8)</td>
<td>123 (50.1)</td>
<td>0.38</td>
</tr>
<tr>
<td>Gastroesophageal junction</td>
<td>9 (3.6)</td>
<td>9 (3.6)</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Histological type</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiomyopathy (Lauren classification)</td>
<td>89 (36.1)</td>
<td>85 (34.5)</td>
<td>0.46</td>
</tr>
<tr>
<td>Intestinal</td>
<td>158 (64.0)</td>
<td>161 (65.7)</td>
<td>0.58</td>
</tr>
<tr>
<td><strong>Number of organs with metastases</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 organ</td>
<td>105 (42.6)</td>
<td>103 (42.0)</td>
<td>0.63</td>
</tr>
<tr>
<td>2 organs</td>
<td>103 (41.6)</td>
<td>102 (41.4)</td>
<td>0.45</td>
</tr>
<tr>
<td>3 or more organs</td>
<td>39 (15.8)</td>
<td>41 (16.4)</td>
<td>0.63</td>
</tr>
</tbody>
</table>

**Efficacy**

- Median OS was 5.32 months with nivolumab vs 4.14 months with placebo (hazard ratio, 0.63; 95% CI, 0.48–0.80; p < 0.0001).

- **ORR**: 20.7% with nivolumab vs 9.4% with placebo (p = 0.003).

- **DCR**: 52.5% with nivolumab vs 33.8% with placebo (p = 0.003).

### Safety

- **TRAEs in > 2% of patients treated**
  - AST increased: 35.3% vs 27.1%
  - Anorexia: 29.8% vs 22.8%
  - Rash: 17.2% vs 9.8%

### Conclusions

- Nivolumab significantly prolonged median OS compared with placebo (5.32 vs 4.14 months, respectively; hazard ratio, 0.63; 95% CI, 0.48–0.80; p < 0.0001).

### References


### Acknowledgments

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