The objective of this investigation was to assess the effect of OCR on specific humoral immunity in patients with OPERA I and OPERA II were two identical Phase III, randomized, double-blind, double-dummy, active-controlled studies. The studies were supported by the Canadian Institute for Health Research, Genzyme, F. Hoffman-La Roche Ltd, Michael Smith Foundation, and the MS Society of Canada.

METHODS

Study Design

- Patients were men or women aged 18–55 years with RRMS from the OPERA I and OPERA II studies.
- Eligible patients were stratified by region (USA vs rest of world) and baseline Expanded Disability Status Scale (EDSS) of 0.0–5.5.
- All patients received intravenous methylprednisolone 100 mg (and optional analgesics/antipyretics and antihistamines) prior to infusion for vaccination; immunizations were to be completed ≥6 weeks prior to treatment.
- B-cell monitoring occurred if B cells are not repleted.
- The proportion of patients with positive levels of Ab against mumps virus at baseline was 94.1% and 93.6% in the p-INF β-1a and OCR groups, respectively.
- The proportion of patients with positive levels of Ab against rubella virus at baseline was 87.9% and 89.0% in the p-INF β-1a and OCR groups, respectively.

RESULTS

- The proportion of patients with positive levels of Ab against rubella virus at baseline was 95.5% in both treatment groups.
- The proportion of patients with positive levels of Ab against rubella virus was 95.5% in both treatment groups.

DISCLOSURES

- Presented at the 2016 Annual Meeting of the Consortium of Multiple Sclerosis Centers (CMSC); National Harbor, MD, USA; June 1–4, 2016.
- The proportion of patients with positive levels of Ab against rubella virus at baseline was 95.5% and 94.1% in the IFN β-1a and OCR groups, respectively.
- The proportion of patients with positive levels of Ab against rubella virus at baseline was 95.5% and 94.1% in the IFN β-1a and OCR groups, respectively.
- All patients received 100 mg methylprednisolone intravenously (and analgesics/antipyretics and antihistamines) prior to infusion for vaccination; immunizations were to be completed ≥6 weeks prior to treatment.

ACKNOWLEDGMENTS

- The proportion of patients with positive levels of Ab against rubella virus at baseline was 95.5% and 94.1% in the IFN β-1a and OCR groups, respectively.

REFERENCE


Table 1. The proportion of patients with positive levels of Ab against varicella zoster virus over the 96-week treatment period

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Baseline</th>
<th>Week 12</th>
<th>Week 24</th>
<th>Week 48</th>
<th>Week 72</th>
<th>Week 96</th>
</tr>
</thead>
<tbody>
<tr>
<td>p-INF β-1a</td>
<td>94.1%</td>
<td>95.5%</td>
<td>95.5%</td>
<td>95.5%</td>
<td>95.5%</td>
<td>95.5%</td>
</tr>
<tr>
<td>OCR</td>
<td>93.6%</td>
<td>95.5%</td>
<td>95.5%</td>
<td>95.5%</td>
<td>95.5%</td>
<td>95.5%</td>
</tr>
</tbody>
</table>

CONCLUSIONS

- Ocrelizumab did not appear to have an effect on specific humoral immunity (Ab titer) to common bacterial and viral antigens (mumps virus, rubella virus, varicella zoster virus, and Streptococcus pneumoniae) in patients with RRMS during the controlled treatment periods of the RMS studies.
- Future assessment of the impact of changes in immunization guidelines on patients with RRMS is warranted.