RESULTS

The Avonex Combination Trial (ACT) was an industry-sponsored, investigator-run clinical trial that evaluated oral methotrexate and intravenous methylprednisolone as adjunctive therapies for relapsing-remitting MS patients with continuing disease activity on interferon beta-1a monotherapy. ACT observed 313 subjects for one year at 72 clinical sites.

Table 1. Comparison of subject baseline characteristics and on-study activity.

<table>
<thead>
<tr>
<th>University based clinics (n=28)</th>
<th>Multispecialty groups (n=6)</th>
<th>Community practices (n=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients enrolled (total, mean per site)</td>
<td>115.4</td>
<td>22.3</td>
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<tr>
<td>Age (y, mean ± SD)</td>
<td>40.5 ± 6.8</td>
<td>42.4 ± 8.4</td>
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<td>Sex (% female)</td>
<td>73.9</td>
<td>95.5</td>
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<td>Years from onset (mean ± SD)</td>
<td>8.8 ± 6.5</td>
<td>8.9 ± 6.9</td>
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<td>Years from diagnosis (mean ± SD)</td>
<td>5.7 ± 4.8</td>
<td>5.8 ± 4.1</td>
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<td>EDSS (mean ± SD)</td>
<td>2.5 ± 1.1</td>
<td>2.7 ± 1.5</td>
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<tr>
<td>T25FW (sec, mean ± SD)</td>
<td>5.7 ± 2.7</td>
<td>7.6 ± 7.7</td>
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<tr>
<td>9HPT (sec, mean ± SD)</td>
<td>22.5 ± 5.4</td>
<td>24.1 ± 9.4</td>
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<tr>
<td>PASAT3 (% correct, mean ± SD)</td>
<td>48.5 ± 11.8</td>
<td>48.5 ± 10.4</td>
</tr>
<tr>
<td>Relapses prior 3 years (mean ± SD)</td>
<td>2.4 ± 1.6</td>
<td>2.1 ± 1.4</td>
</tr>
</tbody>
</table>

Qualifying event:

- Relapse only (%) | 60.9 | 50.0 | 60.4 |
- GdE MRI brain only (%) | 8.7 | 0.0 | 0.7 |
- GdE MRI spine only (%) | 0.9 | 0.0 | 0.7 |
- Relapse and GdE MRI brain/spine (%) | 20.6 | 31.8 | 26.0 |
- MRI measures:
  - T2-volume (cm³, quartiles) | 1.72, 5.67, 12.39, 0.70, 2.24, 7.38, 1.33, 4.26, 11.90 |
  - T1-volume (cm³, quartiles) | 0.21, 0.99, 3.26, 0.13, 0.40, 1.28, 0.14, 0.67, 2.96 |
  - BPF (mean ± SD) | 0.816 ± 0.024, 0.819 ± 0.025, 0.814 ± 0.024 |
  - GdE lesion number (mean ± SD) | 0.56 ± 1.52, 0.36 ± 1.14, 0.53 ± 1.50 |
  - Percent with ≥1 GdE lesion | 20.0 | 14.6 | 22.4 |
  - N/E T2 lesions (% mean ± SD) | 2.0 ± 3.2 | 1.9 ± 3.1 | 1.2 ± 2.7 |

Relapse rate (pooled estimate ± SE): 0.37 ± 0.07

*p = 0.05
**adjusted p = 0.001
***adjusted p = 0.21

Although subject baseline characteristics were comparable at university-based clinics, multispecialty groups, and community neurology practices, on-study activity differed.

CONCLUSIONS

- Aggregate performance did not suggest systematic differences in simple measures of site performance based on subject recruitment-retention, adherence to protocol, and data quality and responsiveness to queries.
- Community practices initiated more rapidly than university-based clinics and multispecialty groups and accepted lower per-subject reimbursement than multispecialty groups.

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See the AAN listing for detailed Conflict of Interest information.

DISCLOSURES

The coordinating center site (Cleveland Clinic Foundation, a multispecialty group) was excluded from the analysis.

Site categorization:

1. University based clinic (n=28)
2. Multispecialty group (n=6)
3. Community neurology solo or group practice (n=37)

METHODS

Site categorization:

1. University based clinic (n=28)
2. Multispecialty group (n=6)
3. Community neurology solo or group practice (n=37)

No significant differences were found among site types on measures of subject recruitment-retention, adherence to protocol and data quality and responsiveness to queries except for relapse rate (p = 0.003) and percent with ≥1 GdE lesion (p = 0.004).

Figure 3. Community practices vs. other site types on Factor 2 performance measures.