Early treatment with prednisolone or acyclovir in Bell’s palsy
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Study Type: POEM
Purpose: Whereas Bell’s palsy affects 11 to 40 patients/100,000 per year, and 30% have a poor recovery as noted by facial disfigurement, pain, and psychological difficulties, and a Cochrane review reveals insufficient data on treatment, the NIH for Health Research in England commissioned an independent academic group to determine if early use of acyclovir or prednisolone would improve chances of recovery.

Study Duration: 9 month follow-up for patients, study ran 2 years

Trial Design: Prospective, 2 times randomized, double-blinded, placebo-controlled trial, intention-to-treat, multicenter (17 referral hospitals in Scotland); all patients outpatient diagnosed, medications were given free

Medications: 4 groups, 10 day treatment:
Randomization 1 Randomization 2 (n = ~125 patients in each grp)
Acyclovir 400 mg five times a day + Prednisolone 25 mg bid OR placebo
Placebo + Prednisolone OR placebo

Patients: n = 496, 44 years old, 49% female, 54% got treatment within 24 hours of symptoms, 32% within 48 hrs
Baseline scale scores (see outcomes below): House-Brackman (3.6); Mark 3 Health Utility (0.79); Derriford (73); Brief Pain Inventory (13) – therefore patients had paralysis, but facial appearance was not disfiguring and pain was minimal

Inclusion Criteria: > 16 years old, unilateral facial-nerve weakness with no cause, referred to ENT within 72 hours after onset of symptoms
Exclusion Criteria: pregnancy, breast-feeding, uncontrolled diabetes (HbA1c > 8), PUD, otitis media, herpes zoster, multiple sclerosis, systemic infection, sarcoidosis

Primary outcome: House-Brackman grading system for facial-nerve function – there are 6 grades from grade 1 being normal functioning to grade 6 being severe paralysis
Secondary outcome: quality of life assessment (The Mark 3 - 1 = full health, a negative score means worse than death), facial appearance (Derriford Appearance Scale - high score means distress, 8 to 262), pain (Brief Pain Inventory - high score means increase severity, 0 to 110)

1. Are the results valid?
   * Randomized? Yes
   * Double-blinded? Yes
   * Placebo-controlled? Yes
   * Similar groups? Yes
   * Allocation concealment? Yes
   * Patient accountability? Yes

2. What were the results?

<table>
<thead>
<tr>
<th>Primary outcome</th>
<th>Prednisolone</th>
<th>Placebo</th>
<th>P-value,ARR,NNT</th>
<th>Acyclovir</th>
<th>Placebo</th>
<th>P-value,ARR,NNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1 (no paralysis) – 3 mths</td>
<td>83%</td>
<td>63.6%</td>
<td>&lt;.001, 19%, 6</td>
<td>71.2%</td>
<td>75.7%</td>
<td>NS</td>
</tr>
<tr>
<td>Grade 1 (no paralysis) – 9 mths</td>
<td>94.4%</td>
<td>81.6%</td>
<td>&lt;.001,12.8%, 8</td>
<td>85.4%</td>
<td>90.8%</td>
<td>NS</td>
</tr>
<tr>
<td>Mark 3 score</td>
<td>0.84</td>
<td>0.88</td>
<td>.04</td>
<td>0.86</td>
<td>0.88</td>
<td>NS</td>
</tr>
<tr>
<td>Pain Inventory</td>
<td>1.36</td>
<td>1.83</td>
<td>NS</td>
<td>1.61</td>
<td>1.72</td>
<td>NS</td>
</tr>
<tr>
<td>Derriford score</td>
<td>40</td>
<td>50</td>
<td>NS</td>
<td>49</td>
<td>43</td>
<td>NS</td>
</tr>
</tbody>
</table>

Other results:
* Patients on double-placebo - 65% were fully recovered at 3 mths and 85% at 9 mths
* When prednisolone was added to placebo or acyclovir, there was efficacy.
* There was no efficacy associated with acyclovir.
* Adverse events were minor and expected.

3. Will the results help me?
   * At 3 months, prednisolone produced complete recovery in 20% more patients than those not on therapy.
   * Acyclovir did not change recovery rates verses placebo

Conclusion: In this outpatient trial, efficacy of placebo is confirmed and generally favorable. Early treatment with prednisolone within 72 hours after onset of symptoms, increases the recovery rate from 65% to 83% at 3 months and 85% to 94% at 9 months. Acyclovir offers no benefit over placebo and there is no extra benefit when added to prednisolone. There was no added benefit of prednisolone for appearance, pain and quality of life. Prednisolone and prednisone are essentially the same, so prescribe Prednisone 50 mg, take ½ tablet twice a day for 10 days. No cost issues, except we save money not using acyclovir (~$30.00).