

Corticosteroids for the Treatment of Bell's Palsy

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CITATION: Sullivan FM, Swan IR, Donnan PT Early treatment with prednisolone or acyclovir in Bell's palsy. N Engl J Med. 2007 Oct 18;357(16):1598-607.

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| I. WHAT IS BEING STUDIED? | CORTICOSTEROID AND ANTIVIRAL AGENTS IN THE TREATMENT FOR BELL'S Palsy |
| 1. Study Objective | To determine if Corticosteroids and/or antivirals are effective in the treatment of Bell's Palsy |
| 2. Study Design | Double-blind, placebo controlled, randomized, factorial trial across mainland Scotland including 17 hospitals and 551 patients from June 2004 to June 2006 with randomization occurring twice via an independent service |
| 3. Inclusion Criteria | Age 16 or greater With unilateral facial-nerve weakness of no identifiable cause who could be referred to a collaborating ENT within 72 hrs. of symptoms |
| 4. Exclusion Criteria | Pregnancy, breast-feeding, uncontrolled diabetes (Hemoglobin A1c >8%), PUD, suppurative otitis media, herpes zoster, multiple sclerosis, systemic infection, sarcoidosis, other rare conditions |
| 5. Interventions Compared | Acyclovir 400mg 5 times daily for 10 days vs. Prednisolone 25mg twice daily for 10 days vs. combination of two for 10 days vs. placebo-placebo for 10 days |
| 6. Outcomes Evaluated | Primary: Improvement on the House-Brackmann grading system for facial-nerve function Secondary: Health-related quality of life, |

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| | <p>facial appearance, pain</p> <p>Outcomes measured at 3 months and again at 9 months if incomplete recovery</p> |
| II. Are the results of the study valid? | |
| 1. Was the assignment of patients randomized? | Yes, patients randomly assigned to corticosteroid or acyclovir group and then randomly assigned again to receive placebo or actual drug |
| 2. Were all patients who entered the trial properly accounted for and attributed at its conclusions? | Yes, Although 55 of the 551 eligible patients dropped out of study before final House-Brackmann grade, these subjects underwent intention-to-treat analysis |
| 3. Was follow-up complete? | It was complete for the 496 on which the calculations were based |
| 4. Were patients, health workers and study personnel “blind” to treatment? | Yes, only the pharmaceutical company and the 17 hospital pharmacies had access to codes for the colorless, odorless capsules each participant was given |
| 5. Were study groups similar at the start of the trial? | Yes, 253 male and 243 females close to evenly divided into the four study groups. Average age was 44 with a range of + or – 16.4, average score on House-Brackmann scale was 3.6+ or- 1.6 |
| 6. Aside from the experimental intervention, were the groups treated equally | Yes, there is not any evidence of the groups receiving differing treatments except what is documented for the study |
| III. What were the results? | |
| 1. How large was the treatment effect? (difference between treatment and control group). | <p>Primary outcome: at 3 mo. 83% of patients who received prednisolone had complete recovery, 63.6% for those who did not receive prednisolone (95% confidence interval [CI], 11.7 to 27.1; P<0.001). No statistical difference for acyclovir during same time frame 71.2 vs. 75.7 respectively(95% CI, –12.4 to 3.3). At nine months prednisolone recipients had 94.4% recovery and 81.6% without (95% CI, 7.2 to</p> |

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| | <p>18.4; $P < 0.001$). acyclovir 85.4 with and 75.7 without – again the acyclovir group was not statistically significant</p> <p>those receiving both acyclovir and prednisone had 79.7 at 3 mo. and 92.7 at 9 mo. complete recovery</p> <p>double placebo at 3 mo. 64.7% complete recovery and 85.2% at 9 mo.</p> <p>there were no drug-drug interactions with acyclovir and prednisolone, only minor adverse events such as nausea, diarrhea, constipation, etc. occurred with the study drugs</p> <p>NNT: At 3 months, the absolute risk reduction associated with prednisolone treatment was 19%. Therefore, the number needed to treat in order to achieve one additional complete recovery was 6 (95% CI, 4 to 9). At 9 months, the equivalent numbers were an absolute risk reduction of 12% and a number needed to treat of 8 (95% CI, 6 to 14).</p> |
| <p>2. What was the estimated treatment effect at a 95% confidence interval?</p> | <p>See above</p> |
| <p>IV. Will the results help me in caring for my patients? (applicable ?)</p> | <p>Yes, well designed study with sufficient power</p> <p>Results for patients who have significant comorbidities not studied so study not applicable to those populations</p> |
| <p>1. Were all clinically important outcomes considered?</p> | <p>Yes, each participant treated for 10 days and followed up for 9 months</p> |
| <p>2. Are treatment outcomes worth the potential harms?</p> | <p>Yes, when identification of those patients whose symptom onset is within 3 days of beginning corticosteroid therapy. There were no major “harms” identified. Subgroup analysis of diabetics and the effects of steroids were not disclosed</p> |

