



Title	A Randomized Controlled Trial of the Use of Aciclovir and/or Prednisolone for the Early Treatment of Bell's Palsy: The BELLS Study
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Aim

1) To describe the resolution of neurological deficit and cosmetic, psychological, and functional recovery in each of four patient groups: those treated with prednisolone, aciclovir, both, or neither; 2) to determine which group of patients has the greatest reduction in neurological disability scores on the House-Brackmann grading system at 3 and 9 months after randomization; 3) to compare self-reported health status (including assessments of pain) at 3 and 9 months after randomization; and 4) to compare the incremental cost per neurological deficit resolved (case cured) and incremental cost per QALY in the study groups.

Conclusions and results

Of 496 completed patients, 357 had recovered at 3 months. A further 80 had recovered at 9 months, leaving 59 with a residual facial nerve deficit. No significant prednisolone-aciclovir interaction was found at 3 months or at 9 months ($p=0.32$, $p=0.72$ respectively). There were significant differences in complete recovery at 3 months between the prednisolone comparison groups (83.0% for prednisolone, 63.6% for no prednisolone, a difference of +19.4% (95% CI: +11.7% to +27.1%, $p<0.001$). The number needed to treat (NNT) to achieve one additional complete recovery was 6 (95% CI: 4 to 9). No significant difference was found between the aciclovir comparison groups (71.2% for aciclovir and 75.7% for no aciclovir, a difference of -4.5% (95% CI: -12.4% to +3.3%, $p=0.30$, adjusted 0.50). Nine-month assessments of patients recovered were: 94.4% for prednisolone compared with 81.6% for no prednisolone, a difference of +12.8% (95% CI: +7.2% to +18.4%, $p<0.001$); the NNT is 8 (95% CI: 6 to 14). Proportions recovered at 9 months are 85.4% for aciclovir and 90.8% for no aciclovir, a difference of -5.3% (95% CI: -11.0% to +0.3%, $p=0.07$, adjusted 0.10). We found no significant differences in our secondary measures apart from HUI3 at 9 months in those treated with prednisolone. The mean cost of prednisolone was 232 pounds sterling (GBP) and the mean cost of no prednisolone was GBP 248. Prednisolone was more ef-

fective in terms of cure and provided on average slightly more QALYs (0.718 versus 0.717). A probabilistic analysis suggested that prednisolone was likely (70%) to be considered cost effective at a GBP 20 000 or GBP 30 000 cost per QALY threshold. Aciclovir was, on average, more costly than no aciclovir (GBP 253 versus GBP 246) and likely to be no more effective in terms of cure and QALYs (0.717 versus 0.718). It was unlikely (15%) to be considered cost effective at a GBP 20 000 or GBP 30 000 cost per QALY threshold.

Recommendations

See Executive Summary link at www.hta.ac.uk/project/1375.asp.

Methods

See Executive Summary link at www.hta.ac.uk/project/1375.asp.

Further research/reviews required

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