CRD summary
This well-conducted review concluded that corticosteroids are associated with a reduced risk of unsatisfactory recovery in Bell palsy. Also, there may be an additional benefit associated with the use of antiviral agents combined with corticosteroid treatment. These conclusions are likely to be reliable.

Authors' objectives
To assess the association between use of corticosteroids and antiviral agents and the risk of unsatisfactory facial recovery in patients with Bell palsy.

Searching
MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, CINAHL, PsycINFO and Web of Science were searched without language restrictions up to March 2009. PapersFirst, ProceedingsFirst and ProQuest were searched for unpublished studies. Some search terms were reported. References of relevant articles were checked, experts were contacted and www.clinicaltrials.gov was searched.

Study selection
Randomised controlled trials (RCTs) that compared treatment with corticosteroids or antiviral agents with a control (placebo, no treatment, supportive treatment or an active treatment also given to the intervention group) in patients diagnosed with Bell palsy were eligible for inclusion. The primary review outcome was unsatisfactory facial recovery after at least four months. Secondary outcomes were: unsatisfactory short term recovery at between six weeks and four months; synkinesis and autonomic dysfunction; major life-threatening adverse effects; and minor adverse effects. Unsatisfactory recovery was defined as failure to achieve complete or near-normal recovery.

Included trials assessed corticosteroid or antiviral monotherapy, or combined therapy. Treatments administered were acyclovir, deflazacort, dexamethasone, methylprednisolone, prednisone, prednisolone and valacyclovir. Control groups received placebo, supportive treatment, no treatment, or another assessed treatment. A variety of instruments were used to measure the primary outcome, these included: House-Brackmann, Facial Paralysis Recovery Profile/Index, Sunnybrook, Yanagihara, Modified Adour Mechelse, and other instruments.

Two reviewers independently assessed the studies for inclusion. Disagreements were resolved through consensus.

Assessment of study quality
Two reviewers assessed the studies for validity using the following Cochrane based criteria: randomisation, allocation concealment, blinding, loss to follow-up, selective reporting and other biases. For each outcome the issues of bias, precision, consistency, directness and publication bias were considered.

Data extraction
Two reviewers extracted the data in order to calculate relative risks with 95% confidence intervals, and resolved inconsistencies through consensus. Authors were contacted for further information. Where outcomes were reported at multiple time points the earliest time point was used for assessment of short-term recovery and the latest time point for long-term recovery.

Methods of synthesis
Trials were combined in a meta-analysis and pooled relative risks with 95% confidence intervals were calculated using a Mantel-Haenszel random effects model. Statistical heterogeneity between studies was assessed using the I² and X² statistics. Trials with a factorial design were treated as two separate trials. Interactions between corticosteroids and antiviral agents were investigated using a logistic regression analysis. Other variables were also defined a priori (initial
severity, dose, time to treatment, and study blinding); z scores were calculated to assess the significance of these interactions. Numbers-need-to-treat or numbers-needed-to-harm and their 95% confidence intervals were calculated using baselines derived from observational data and/or median control group values. Publication bias was assessed using funnel plots and the Egger test.

**Results of the review**

Eighteen randomised controlled trials (RCTs) were included in the review (n=2,786 participants); eight trials assessed corticosteroids, seven trials assessed antiviral agents, and three trials assessed both interventions. The mean sample size was 155 (range 40 to 829). Median follow-up was six months (range 10 weeks to 12 months). Six trials failed to describe randomisation sequence generation. Seven trials did not adequately report allocation concealment. Ten trials used blinded outcome adjudicators. Six trials used an intention-to-treat analysis, or a variant of this. Four trials reported loss to follow-up of more than 20%. The quality of the evidence was considered to be high for the impact of corticosteroids on outcomes of unsatisfactory recovery and synkinesis and autonomic dysfunction, and moderate for other outcomes.

**Corticosteroid monotherapy:** There was a statistically significantly lower risk of unsatisfactory recovery with corticosteroid treatment alone (relative risk 0.69, 95% confidence interval (CI): 0.55 to 0.87; number-need-to-treat 11, 95% CI: 8 to 25; 10 RCTs).

**Antiviral monotherapy:** There was no statistically significant difference between groups treated with antiviral agents alone and control groups (two RCTs).

**Combined corticosteroid and antiviral therapy:** Antiviral agents plus corticosteroids were significantly more effective than antivirals alone (relative risk 0.48, 95% CI: 0.29 to 0.79; number-need-to-treat 6, 95% CI: 4 to 14; two RCTs). There was a trend towards greater efficacy for antiviral agents plus corticosteroids to be more effective than corticosteroids alone (relative risk 0.75, 95% CI: 0.56 to 1.00; number-need-to-treat 20, 95% CI: 11 to ∞; eight RCTs).

There was no evidence of significant statistical heterogeneity in any of the analyses, with the exception of antivirals alone (I²=47%).

There was a statistically significant effect of dose with corticosteroid treatment, with higher doses (over 450 mg) associated with a larger treatment effect (p=0.02). No significant interactions were found with other variables.

Corticosteroids, but not antivirals were associated with a significant benefit in short term recovery and reduction in synkinesis and autonomic dysfunction. There was no evidence for significant adverse events associated with either treatment (nine RCTs).

There was no evidence of publication bias.

**Authors’ conclusions**

Corticosteroids were associated with a reduced risk of unsatisfactory recovery in Bell palsy. There may be an additional benefit associated with the use of antiviral agents combined with corticosteroid treatment.

**CRD commentary**

The review question and inclusion criteria were clear. The search was extensive and included a systematic search for unpublished studies. These factors, together with the lack of language restrictions, reduced the chances that relevant studies were omitted. The authors reported using methods designed to reduce reviewer bias and error at all stages of the review process. An appropriate and thorough validity assessment was conducted and the results were used to inform the synthesis. The statistical synthesis was conducted appropriately. Heterogeneity was assessed and explored. The authors correctly noted that the meta-analysis was heavily influenced by two large trials. The authors’ conclusions accurately reflect the results of the review and are likely to be reliable.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.
Research: The authors stated that further primary studies were required to confirm or refute an incremental benefit of combined corticosteroid and antiviral therapy over corticosteroid monotherapy for Bell palsy.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.