Vacuna DTP y sindrome de muerte subita del lactante: un metaanalisis [The DTP vaccine and the infant sudden death syndrome: meta-analysis]

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Authors' objectives
To evaluate the risk of sudden infant death syndrome (SIDS) after diphtheria, tetanus and pertussis (DTP) immunisation.

Searching
The following sources were searched: MEDLINE from January 1966 to February 1995, EMBASE from January 1980 to December 1994, and IDIS from January 1985 to February 1995). Reference lists of retrieved review and primary articles were also examined.

Study selection
Study designs of evaluations included in the review
Epidemiological studies (case-control and cohort designs) assessing the risk of SIDS in immunised versus non-immunised infants, or the risk of SIDS up to 30 days post-immunisation versus more than 30 days post-immunisation. Studies from UK, USA and France were included.

Specific interventions included in the review
DTP immunisation.

Participants included in the review
Infants who had been immunised with DTP and those who had not been immunised with DTP were included.

Outcomes assessed in the review
The outcome assessed was the mortality rate from SIDS, with SIDS being diagnosed clinically or at autopsy.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality
The authors do not state that they assessed quality.

Data extraction
An adjusted risk ratio was used for each study if this was available, otherwise a risk ratio was calculated from the raw data.

Methods of synthesis
How were the studies combined?
A pooled risk ratio was calculated comparing immunised and non-immunised infants.

How were differences between studies investigated?
A chi-squared test for heterogeneity was performed. The pooled risk ratio analysis was repeated for the risk of SIDS in DTP-immunised infants versus non-immunised infants, after excluding the study with the least weight in the meta-analysis.
Results of the review
Assessment of the risk of SIDS in DTP-immunised infants versus non-immunised infants was based on: 4 case-control studies (903 infant cases and 2,184 infant controls).

Assessment of the risk of SIDS in the following month to DTP-immunisation was based on: 3 case-control studies (313 infant cases and 1,051 infant controls) and 1 cohort study (90,668 infants).

The pooled risk ratio of SIDS in DTP-immunised infants versus non-immunised infants was 0.67 (95% confidence interval, CI: 0.60, 0.75). The chi-squared test for heterogeneity was 8.97 (p=0.03). Excluding the study with the least weight in the meta-analysis gave a chi-squared value of 1.72 (p=0.42) and a pooled risk ratio of 0.68 (95% CI: 0.61, 0.76).

The pooled risk ratio of SIDS in the following month to DTP-immunisation was 1.00 (95% CI: 0.84, 1.20). The chi-squared test for heterogeneity was 7.86 (p=0.05).

Authors’ conclusions
DTP-immunisation does not appear to increase the risk of SIDS, and the risk of SIDS is not greater in the 30 days following immunisation. These data indicate a lack of association between DTP-immunisation and SIDS.

CRD commentary
This commentary refers to a short 2-page English language version of the original 4-page foreign language (Spanish) article. It is possible that more data are available in the original article.

Three databases were searched but the search strategy was not specified. The primary studies are over an 18-year span, thus the form of the vaccine used and the incidence of SIDS may have varied over this time interval. Relevant details of the primary studies are lacking: the age of immunisation of the infants; the course of immunisation the infants were recommended to have; which dose in the course of immunisations the studies were based on; whether those infants not having DTP-immunisation were excluded on medical grounds from having the immunisation, or whether their parents refused immunisation; the definition of SIDS; the selection of controls; and the source of DTP-immunisation status. There was no assessment of the quality of the primary studies and no discussion of the possible sources of heterogeneity between studies. The time over which data were collected from the primary studies, for assessing the risk of SIDS in the following month to DTP-immunisation, varied from 14 to 30 days; this may have resulted in an underestimate of the number of cases of SIDS. No study after 1986 is included though databases were searched up to 1995. The intervening years may have seen alterations in the immunisation schedules used and in the incidence of SIDS. More information on the primary studies is required before adequate assessment of the evidence is possible.

Implications of the review for practice and research
Ongoing assessment of possible adverse reactions to DTP-immunisation is required.

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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.