Evaluation d'un traitement preventif par RU 41740 (biostim) des infections rhinopharyngees recidivantes de l'enfant [Evaluation of RU 41740 (biostim) for the prevention of recurrent nasopharyngeal infections in pediatric patients]

Reinert P, Morales M, Brin S, Fagnani F

Authors' objectives
To examine the effectiveness of Biostim (RU 41740) for the prevention of recurrent rhinopharyngitis in children.

Searching
The sources searched to identify primary studies were not stated. The French and international literature was searched for studies published before 1994.

Study selection
Study designs of evaluations included in the review
Randomised, double-blind, placebo-controlled studies with follow-up periods of 6 months were included in the review. The studies also reported results at 1, 2, 3 and 6 month intervals.

Specific interventions included in the review
RU 41740 given as 2 mg/day for 8 days and then 1 mg/day for 8 days, 2 months later.

Participants included in the review
Children with recurrent rhinopharyngitis infection (defined as the occurrence of at least 3 infections in the year before inclusion in the study). Children with recurrent tonsillitis or cystic fibrosis were excluded. The age range of the children in the included studies was from 1 to 13 years.

Outcomes assessed in the review
The primary outcome measure was the presence or absence of at least one infection within three months after discontinuation of treatment and the number of such infections. Secondary criteria included: the duration of infection and the severity of the infection (judged by the number and duration of prescribed antibiotics).

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 validity.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.

Methods of synthesis
How were the studies combined?
The average number of infections and percentage of children with infections were combined across the studies and compared using the Mantel-Haenszel chi square test. The relative risk (RR) of at least one infection was calculated for the RU 41740 group compared to the control group. These data were calculated for the entire period of observation (6 months) and for the period of three months following treatment discontinuation.
How were differences between studies investigated?
The authors do not state how differences between the studies were investigated.

Results of the review
Three randomised controlled trials (RCTs) were included in the meta-analysis, providing information on 165 patients.

At 6 months follow-up the average number of infections in the RU 41740 group was statistically significantly lower compared to the control group (1.30 vs. 1.90, p = 0.05), corresponding to a reduction in the average number of infections of 31.6%.

In the 3 months following treatment discontinuation, there was a similar reduction in the average number of infections (0.28 vs. 0.61, p = 0.05). The RR of at least one infection during this time period in the treatment group compared to placebo was 0.56 (p = 0.02).

Cost information
A study which examined the economic and social impact of recurrent respiratory infections in children demonstrated an average direct cost per infection of 358 French Francs compared to a cost per course of RU 41740 of 54 French Francs. Further analyses demonstrated that RU 41740 is economically worthwhile, as long as the reduction in infections is at least 7.9%.

Authors’ conclusions
Given the clinical effectiveness and cost-effectiveness of RU 41740, it is useful for the preventive treatment of recurrent respiratory infections in children.

CRD commentary
This review was of average quality. It addressed a clearly focused question, with explicit criteria for study inclusion, adequate presentation of study details, and appropriate pooling of results. It was limited however by a lack of detail regarding the literature search used, making it impossible to evaluate the comprehensiveness of the search and thereby introducing the possibility of both retrieval bias and publication bias. Furthermore, no validity assessment of the studies appears to have been undertaken. The provision of limited details makes it difficult to assess the validity of the authors’ conclusions, however, given the extremely small sample sizes of the included studies, further, larger trials would be required to determine the role of RU 41740 in these patients.

Implications of the review for practice and research
The authors make no further recommendations for research, however given the small sample sizes of the RCTs included in the review, it seems likely that a larger study is required to fully determine the role of RU 41740 in children with recurrent respiratory infections.

Bibliographic details

Indexing Status
Subject indexing assigned by CRD

MeSH
Adolescent; Bacterial Proteins /therapeutic use; Child; Child, Preschool; Recurrence; Respiratory Tract Diseases /therapy
Record Status
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.