Cochrane Database of Systematic Reviews - - Cochrane Review

Effectiveness of recombinant human Growth Hormone (rhGH) in the treatment of patients with cystic fibrosis.

Code: HTA-32010001118 **Year:** 2010 **Date:** 2012 - updated: 28 JUN 2016 **Author:** Phung OJ

Study design (if review, criteria of inclusion for studies)

Randomised and quasi-randomised studies.

List of included studies (1)

Cohen 2005

Participants

Infants and children (up to 18 years) of both sexes with diagnosis of cystic fibrosis made by either sweat test or genetic testing or clinical criteria, and of any disease severity.

Interventions

Palivizumab

Outcome measures

Adverse events - any; Any serious adverse event; Mortality; Need for hospitalisation for RSV infection; Related adverse events; Related serious adverse event

Main results

One study (186 infants up to two years old) comparing five monthly doses of palivizumab (N = 92) to placebo (N = 94) over one respiratory syncytial virus season was identified and met our inclusion criteria. We judged there to be a low risk of bias with respect to the concealment of the randomization schedule (although it was not clear how this was generated) and to blinding of participants and study personnel. There is also a low risk of bias with regards to incomplete outcome data. However, we judged there to be a high risk of bias from selective reporting (summary statements presented but no data) and the fact that this industry-supported study has not been published as a full report in a peer-reviewed journal. At six months follow-up, one participant in each group was hospitalised due to respiratory syncytial virus; there were no deaths in either group. In the palivizumab and placebo groups, 86 and 90 children experienced any adverse event, while five and four children had related adverse events respectively. Nineteeen children receiving palivizumab and 16 receiving placebo suffered serious adverse events; one participant receiving palivizumab discontinued due to this. At 12 months follow-up, there were no significant differences between groups in number of Pseudomonas bacterial colonisations or change in weight-to-height ratio.

Authors' conclusions

We identified one randomised controlled trial comparing five monthly doses of palivizumab to placebo in infants up to two years old with cystic fibrosis. While the overall incidence of adverse events was similar in both groups, it is not possible to draw firm conclusions on the safety and tolerability of respiratory syncytial virus prophylaxis with palivizumab in infants with cystic fibrosis. Six months after treatment, the authors reported no clinically meaningful differences in outcomes. Additional randomised studies are needed to establish the safety and efficacy of palivizumab in children with cystic fibrosis.

http://effectivehealthcare.ahrq.gov/ehc/products/98/391/rHGH%20Protocol%20(2-9-2010).pdf

See also

Health Technology Assessment Database YR: 2010 NO: 1

Keywords

Antiviral Agents; Child; Infant; Infection; Palivizumab; pharmacological_intervention; Respiratory Syncytial Virus Infections; Respiratory Tract Diseases; Respiratory Tract Infections; Virus; Immunoregulatory; Bronchiolitis;