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Cochrane Database of Systematic Reviews 2005, Issue 4. Art. No.: CD003135.
DOI: [10.1002/14651858.CD003135.pub3](https://doi.org/10.1002/14651858.CD003135.pub3).

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[Intervention Review]

Fluticasone versus placebo for chronic asthma in adults and children

Nick P Adams¹, Janine C Bestall², Toby J Lasserson³, Paul Jones⁴, Christopher J Cates⁵

¹Respiratory Medicine, Worthing & Southlands NHS Trust, Worthing, UK. ²Division of Physiological Medicine, St George's Hospital Medical School, London, UK. ³Community Health Sciences, St George's University of London, London, UK. ⁴St George's Hospital Medical School, London, UK. ⁵Manor View Practice, Bushey Health Centre, Watford, UK

Contact address: Nick P Adams, Respiratory Medicine, Worthing & Southlands NHS Trust, Worthing, UK. Nick.Adams@wash.nhs.uk.**Editorial group:** Cochrane Airways Group.**Publication status and date:** Unchanged, published in Issue 3, 2008.**Citation:** Adams NP, Bestall JC, Lasserson TJ, Jones P, Cates CJ. Fluticasone versus placebo for chronic asthma in adults and children. *Cochrane Database of Systematic Reviews* 2005, Issue 4. Art. No.: CD003135. DOI: [10.1002/14651858.CD003135.pub3](https://doi.org/10.1002/14651858.CD003135.pub3).

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ABSTRACT

Background

Inhaled fluticasone propionate (FP) is a relatively new inhaled corticosteroid for the treatment of asthma.

Objectives

1. To assess efficacy and safety outcomes in studies that compared FP to placebo for treatment of chronic asthma.
2. To explore the presence of a dose-response effect.

Search methods

We searched the Cochrane Airways Group Specialised Register (January 2005), reference lists of articles, contacted trialists and searched abstracts of major respiratory society meetings (1997-2004).

Selection criteria

Randomised trials in children and adults comparing FP to placebo in the treatment of chronic asthma. Two reviewers independently assessed articles for inclusion and methodological quality.

Data collection and analysis

Two reviewers extracted data. Quantitative analyses were undertaken using RevMan 4.2

Main results

Seventy-five studies met the inclusion criteria (14,208 participants). Methodological quality was high. In non-oral steroid treated asthmatics with mild and moderate disease FP resulted in improvements from baseline compared with placebo across all dose ranges (100 to 1000 mcg/d) in FEV1 (between 0.13 to 0.45 litres); morning PEF (between 23 and 47 L/min); symptom scores (based on a standardised scale, between 0.5 and 0.85); reduction in rescue beta-2 agonist use (between 1.2 and 2.2 puffs/day). High dose FP increased the number of patients who could withdraw from prednisolone: FP 1000-1500 mcg/day Peto Odds Ratio 14.07 (95% CI 7.17 to 27.57). FP at all doses led to a greater likelihood of sore throat, hoarseness and oral Candidiasis. Twenty-one patients would need to be treated for one extra to develop Candidiasis (FP 500 mcg/day), whilst only three or four patients need to be treated to avoid one extra patient being withdrawn due to lack of efficacy at all doses of FP.

Authors' conclusions

Doses of FP in the range 100-1000 mcg/day are effective. In most patients with mild-moderate asthma improvements with low dose FP are only a little less than those associated with high doses when compared with placebo. High dose FP appears to have worthwhile oral-corticosteroid reducing properties. FP use is accompanied by an increased likelihood of oropharyngeal side effects.

PLAIN LANGUAGE SUMMARY

Fluticasone is a well-established inhaled steroid for use a preventative agent in controlling asthma symptoms. This review found that it is highly effective even in low doses. The effect does appear to increase with higher doses, but these improvements are small. This drug is associated with symptoms such a thrush, sore throat and hoarseness and these get worse with higher doses. In people with severe asthma who need oral steroid tablets to control their asthma, it can reduce the dose of oral steroids they need and improve their asthma at the same time. However, high or very high doses are needed for this effect. The drug appears to work in children and adults.