**Title**

Systematic review of adverse effects associated with vilanterol in paediatric asthmatic patients

**Authors**

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**Introduction**

Ultra-long-acting β2-agonists (uLABAs) have been recently introduced in asthma, but are not currently included in paediatric guidelines. Potential adverse effects (AEs) of uLABAs are not well reported in children.

**Aims**

To undertake a systematic review of the safety of uLABA vilanterol in paediatric patients.

Primary outcome: AEs from trials of vilanterol in patients <18 years of age

Secondary outcomes: AEs related to cardiovascular risks; Adherence to medication; Frequency of exacerbations; Duration of follow-up

**Methods**

Asthmatic patients <18 years of age and vilanterol (drug, compound GW642444 or brand name Revlar Ellipta) were included in the systematic review. The following databases were searched: Cochrane Database, clinicaltrials.gov, Medline, EMBASE, Pubmed, CINAHL.

**Results**

Of the 239 results, three were included in the analysis, capturing 510 patients, age range 5-11 years. Vilanterol dose (range here) and comparator varied (give some examples here), and quantitative analysis was not performed. There were x (y%) AEs and ADRs reported in children using vilanterol, compared with z (a%) in children on placebo and b (C%) in children on comparator drugs. Cardiovascular next.

Adherence and asthma exacerbations were not reported in all the trials. Follow up result.

Fourteen trials included patients from 12 years of age, but these data were not reported separately from the adults, and were therefore excluded.

**Conclusion**

The frequency and type of AE’s reported with vilanterol are reassuring. But with only 510 children recruited, the power of these studies to detect ADRs that are Uncommon ( (≥1/1,000 to <1/100) or less is insufficient.