

# Safety and tolerability of inhaled budesonide in children in the Steroid Treatment As Regular Therapy in early asthma (START) trial

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The safety and tolerability of asthma medications are still a concern to many asthma patients receiving long-term treatment. Therefore, more safety data from long-term, controlled trials are needed. The aim of this study was to evaluate the safety and tolerability of long-term treatment with once-daily budesonide in children aged 5-10 yrs with mild persistent asthma of recent onset in the inhaled Steroid Treatment As Regular Therapy in early asthma (START) study. Children aged 5-10 yrs with early asthma were randomized to double-blind treatment with budesonide 200 µg or placebo once daily via Turbuhaler<sup>®</sup> in addition to usual asthma therapy, for 3 yrs. Adverse events were recorded from both spontaneous reports and responses to standard questions, and asthma-related events and asthma control were recorded between visits and subsequently graded by the blinded investigators. Of the study population of 1981 children (1004 budesonide and 977 usual care), 81% (812 of 1004) in the budesonide g