Guideline topic: Pharmacological management of asthma
Evidence table 4.8c: Children with poor asthma control on ICS – Is addition of leukotriene receptor antagonists helpful?

Author	Year	Study type	Quality rating	Population	Outomes measured	Effect size	Confidence intervals / p values	Comments
Simons FER et al[1]	2001	RCT, multicentered, placebo controlled, crossover study	++	279 Asthmatic children 6-14 years, with symptoms despite BUD 400mcg/day. Children given montelukast 5mg OD or placebo for 4 weeks and then 'crossed over' treatments	1] FEV1 compared with baseline 2] Home PEFR monitoring 3] asthma attack rates 4] beta2 agonist usage 5]QOLY 6] parent's global assessment 7] physician's global assessment 8] blood eosinophils	***Compared with placebo** 1] difference FEV1 1.3% , p=0.06 (1.9%, p=0.01 – per protocol) 2] difference PEFR am 9.7L/min, p=0.023, and PEFR pm 10.7L/min, p=0.012 3] montelukast 12.2 % versus 15.9% for placebo, p<0.001 4] montelukast reduced beta2 use by mean 0.33puffs/day, p=0.013 5] NS different from placebo	1] 95%ci –(0.1,2.7) 2] 95%ci; (1.4,18.1) for am and (2.4,1 9) for pm P<0.001	No washout period in crossover study but outcome measured in 2nd half of each study period. Benefits of additional montelukast while statistically significant are at best modest

						6] NS different from placebo 7] NS different from placebo 8] 8% reduction greater than placebo		
Bisgaard Hans et al[2]	1999	RCT, crossover, double blind	+	26 asthmatic children, 6-15 years, 11 on ICS, 15 ICS naïve Given 2 weeks montelukast 5mg or placebo then crossover	1] Exhaled NO 2] FEV1 and MMEF	***only those on ICS (n=11)** 1] 22% fall ENO (placebo) 23.6% fall ENO (monte) 2] NS tendency for better values with montelukast		Small subgroup analysis for children on ICS

1. Simons FE, Villa JR, Lee BW, Teper AM, Lyttle B, Aristizabal G, et al. Montelukast added to budesonide in children with persistent asthma: a randomized, double-blind, crossover study. J Pediatr 2001;138(5):694-8.
2. Bisgaard H, Loland L, Oj JA. NO in exhaled air of asthmatic children is reduced by the leukotriene receptor antagonist montelukast. Am J Respir Crit Care Med 1999;160(4):1227-31.