

GUIDELINE TOPIC: PHARMACOLOGICAL MANAGEMENT OF ASTHMA
QUESTION: EVIDENCE TABLE 4.24B: OTHER PREVENTOR THERAPIES - CHROMONES IN CHILDREN AGED <5

BIBLIOGRAPHIC CITATION	STUDY TYPE	EVIDENCE LEVEL	NUMBER OF PATIENTS	PATIENT CHARACTERISTICS	INTERVENTION	COMPARISON	LENGTH OF FOLLOW-UP	OUTCOME MEASURE	EFFECT SIZE	SOURCE OF FUNDING	ADDITIONAL COMMENTS
Glass, J., Archer, L. N. J., Adams, W. and Simpson, H.. Nebulised cromoglycate, theophylline, and placebo in preschool asthmatic children. Archives of Disease in Childhood 1981;56:648-651.	RCT	+	16 children	<5 years. 11 boys, 5 girls. 1 yr 9 months - 4 yrs 5 months. 15 atopic. Viral induced in 15, exercise 11, 7 skin test +ve. 39 hospital admissions. No ICS. All had x2 wheezing episodes in the 6 weeks preceding the trial.	Neb DSCG 20mg qid (vs theophylline 6.7mg qid) vs placebo. Three 8 week treatment periods.	DSCG vs theophylline vs placebo	24 weeks.	Asthma score (scale 0-3). PEFR unreliable and excluded. Bronchodilator use (neb), short term steroids, hospital admissions.	DSCG, Placebo, p (Friedman statistics) Sleep 2.10, 1.92, 2.82. Cough 3.44, 3.96, 0.25. Wheeze 2.35, 2.21, 0.96. Activity 1.45, 2.10, 0.68. Bronchodilator use/wk 1.71, 1.38, 0.25.	Supported by Fisons and Warner-Lambert company for drugs, nebs, stats advice.	This is a negative study. If anything problems with concealment would have had the opposite effect, so probably that DSCG had no real effect in this group.
Hiller, E. J. and Milner, A. D.. Betamethasone 17 valerate aerosol and disodium chromoglycate in severe childhood asthma. British Journal of Diseases of the Chest. 1975;69;103-6.	RCT	+	11 children. 9 boys 2 girls.	Mean age 11 yrs 8 months (range 9y9m - 13y10m). Recurrent wheeze for 6.5 yrs, 7 previous systemic steroids. Extrinsic asthma. No systemic steroids. Poor current status on DSCG and bronchodilator.	Betamethasone 17 Valerate MDI 200mcg qid, or DSCG 20mg cap qid or placebo.	Beta vs dscg vs placebo. Month of each possible. Only last 2 weeks of each period studied.	4 months	Asthma score (ref given). PEFR. Bronchodilator use. FEV0.75 and FVC.	DSCG, placebo, p Symptom score: 2.91, 3.93, <0.005 PEFRam: 50, 52, ns . PEFRpm 58, 60, <0.05 PEFR 2 week: 65, 53, <0.05.	Manufacturers prepared placebos.	The study demonstrates a small but significant benefit to DSCG over placebo. The clinical significance of this is difficult to assess.

									FEV0.75: 65, 58, <0.05 FVC 84, 82, ns.		
Hiller, E. J., Milner, A. D. and Lenney, W.. Nebulized sodium cromoglycate in young asthmatic children. Double-blind trial. Archives of Disease in Childhood. 1977:52:875-6.	RCT	++	17 - cross over	14 boys, 3 girls. Mean age 3 yrs, 5 moths (2y 3m - 4y, 6m). Triggers viral RTI 17, exercise 15, excitement 10, skin test +ve 13.	DSCG neb 20mg qid or placebo.	DSCG vs placebo	18 weeks (2 week run in period of placebo, then 2 months DSCG, 2 months placebo - randomized)	Night/Day time cough/wheeze. PEFr. Parental opinion.	DSCG, placebo, p. Night wheeze 157, 152, ns. Night cough 100, 90, <0.01 Day Wheeze 153, 150, ns. Day cough 98, 93, <0.05. PEFR 100, 96, ns. 11 parents preferred DSCG (inconsistent with score in 6)	Not stated. Placebos supplied by ?	The scoring system is not validated. It is not clear how important the difference found were. No effect on wheeze, just cough and effect appears v. small despite qid DSCG over 2 months. Weak, if any real effect from DSCG over placebo.
Tasche, M. J., van der Wouden, J. C., Uijen, J. H., Ponsioen, B. P., Bernsen, R. M., van Suijlekom-Smit, L. W. and de Jongste, J. C.. Randomised placebo-controlled trial of inhaled sodium cromoglycate in 1-4-year-old children with moderate asthma.[see comment][erratum appears in Lancet 1998 Jan 31;351(9099):376]. Lancet. 1997:350;1060-4.	RCT	++	218 completed in 167 109 DSCG, 109 Placebo	Age 1-4 yrs Moderate asthma. If inhaled or oral steroids classified as severe asthma Questionnaire used to confirm asthma Community based (151 GPs in Rotterdam)	DSCG 10mg MDI + spacer + mask tds vs placebo	DSCG vs Placebo Study medication for 5 months.	5 months.	Symptom score. Symptom free days in months 2-5 of treatment.	DSCG vs placebo (95% CI) Symptom free days: 65.7% vs 64.3% (-8.46 to 5.70) Baseline adjusted sym free day (-4.6 to 7.7) Kids > 80% compliance (-8.21 to 6.41) GP visits 61% vs 85% (p=0.14)	Netherlands Asthma Foundation	Yes No benefit in this age group.