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Title: Maintenance and reliever combination budesonide/formoterol therapy in asthma patients at risk of severe exacerbations: A randomised controlled trial

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Body: Background The Single budesonide/formoterol inhaler Maintenance And Reliever Therapy (SMART) regimen reduces severe asthma exacerbations,but it is uncertain whether it increases risk of adverse effects due to high corticosteroid and beta-agonist doses with both short-term & cumulative exposure. Aim To determine the efficacy & safety of the SMART regimen in asthma patients at risk of severe exacerbations. Methods A 24-week,open-label,multicentre RCT randomised 303 asthma patients with a recent exacerbation to budesonide/formoterol according to SMART or a fixed-dose regimen with salbutamol as reliever (‘Standard’),with electronic monitoring of inhaler use. The primary outcome was the proportion of participants with ≥1 high beta-agonist use episode (>12 actuations/day budesonide/formoterol in SMART or >16 actuations/day salbutamol in Standard). Results There was no significant difference between groups in the primary outcome: SMART 84/151 (56%) v Standard 68/152 (45%) participants; Relative risk (95% CI) 1.24 (0.99-1.56). Days with high use [5 v 9 days/patient, Relative rate (RR) 0.58 (0.39-0.88)] & days with high use without medical review [9 v 18 days/high use patient, RR 0.49 (0.31-0.75)] favoured SMART. SMART resulted in higher ICS exposure,but reduced oral corticosteroid exposure,with no difference in composite systemic corticosteroid exposure [ratio of means 1.03 (0.86-1.22)]. SMART participants had fewer severe asthma exacerbations [35 v 66, RR 0.54 (0.36-0.82)]. Conclusion The SMART regimen has a favourable risk/benefit profile in patients at risk of severe asthma exacerbations. Funding The Health Research Council of New Zealand.