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Title: Short term glucocorticoid therapy in acute exacerbations of chronic obstructive pulmonary disease: "REDUCE**", a non-inferiority multicenter trial. (*Reduction in the Use of Corticosteroids in Exacerbated COPD; ISRCTN19646069)

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Body: Background: The optimal dose and duration of systemic glucocorticoid therapy for acute exacerbations of COPD (AECOPD) is unknown. In this trial, we aimed to demonstrate non-inferiority of 5-days vs 14-days of systemic glucocorticoids with respect to COPD exacerbation. Methods: Patients admitted to hospital with AECOPD were randomized to receive 40mg of prednisone-equivalent daily for either 5 or 14 days in a placebo-controlled fashion. Follow-up was 180 days. The primary endpoint was time to next exacerbation. Results: Of 721 evaluated patients, 327 underwent randomization, and 304 completed the study. Mean age was 63.9 ±23.2 years; mean FEV1%predicted 31.5 ±14.3% and 60.8% were male. Exacerbations occurred in 36.8% and 38.4% of patients in the 5 day and 14 day treatment arms, respectively (p=0.81). Time to exacerbation did not differ between groups in the intention-to-treat and per-protocol analyses (hazard ratios for the short treatment arm, 0.92 [95%-CI, 0.64 to 1.34; p=0.67] and 0.91 [95%-CI, 0.63 to 1.32; p=0.62], respectively); nor did time to death or the combined endpoint of

exacerbation and/or death, with both hazard ratios for the short treatment arm being <1 as well. With respect to the primary outcome, short treatment was not inferior to conventional treatment, since the 95%-confidence intervals did not include the predefined non-inferiority threshold of 1.515. Conclusion: In AECOPD, 5-day treatment with systemic glucocorticoids is non-inferior to 14-day treatment with regard to re-exacerbation during 6 months of follow-up.