Additional file 5. Safety tables for systemic glucocorticoid regimens

Tables 5A and 5B in full. Table 5A covers regimens in which only the intervention arm received a glucocorticoid; Table 5B covers trials in which both arms did, so those comparisons estimate the effect of adding another agent or changing the regimen and cannot be attributed to the glucocorticoid itself. Referred to in the Results.

2. Safety tables

Table 5A. Regimens in which only the intervention arm received a glucocorticoid

Trial	Regimen	Comparator	n	Observation	Serious adverse events	Serious infections	Diabetes / impaired glucose tolerance	Discontinuation for adverse events	Deaths
TESTING	Methylprednisolone 0.6–0.8 mg/kg/d then tapered, 6–8 months; reduced-dose phase 0.4 mg/kg/d, 6–9 months	Placebo	257 vs 246	Median 3.5 years	28 (10.9%) vs 7 (2.8%); full-dose phase 22/136 (16.2%) vs 4/125 (3.2%); reduced-dose phase 6/121 vs 3/121	17 vs 3	Prespecified outcome; group counts are reported in the trial's supplementary appendix, **which was not extracted for this review**	Not reported in the main report; prespecified safety outcomes are tabulated in the supplementary appendix, **not extracted here**	Fatal serious adverse events 4 (all infection-related) vs 0 reported; **all-cause deaths by group not reported**
Katafuchi 2003	Prednisolone 20 mg/d tapered to 5 mg/d over 2 years	Control	43 vs 47 analysed	65±25 vs 64±23 months	Not reported	Not reported	Not reported	1 participant refused after 8 months because of side effects	Not reported
Lv 2009	Prednisone 0.8–1.0 mg/kg/d ×8 weeks then tapered	Cilazapril alone	33 vs 30	Mean 27.3 months	Not reported	0 in the glucocorticoid arm (stated)	0 in the glucocorticoid arm (stated)	Not reported	Not reported
STOP-IgAN	Prednisone 6 months (high-GFR stratum, n=55) or methylprednisolone pulses + prednisolone + cyclophosphamide, then azathioprine (low-GFR stratum, n=27)	Supportive care	82 vs 80	3 years	≥1 event 29 vs 21	Infection-related 8 vs 3	9 vs 1	Not reported by arm	1 vs 1
Ballardie 2002	Prednisolone 40 mg/d tapered + cyclophosphamide then azathioprine	No immunosuppression	19 vs 19	2–6 years	Not reported	Not reported; 1 pulmonary tuberculosis	1 secondary diabetes	Drug-related 2 (marrow suppression, diabetes) and 1 unrelated injury = 3	1 in each arm, after exiting the trial

Table 5B. Trials in which both arms received a glucocorticoid — these comparisons estimate the effect of adding another agent or changing the regimen, and cannot be attributed to the glucocorticoid itself.

Trial	Added agent / change	n	Observation	Serious adverse events	Serious infections	Other
Pozzi 2010	Azathioprine added to the same schedule	101 vs 106	Median 4.9 years	Not reported	Any infection 5 vs 3 (not described as serious)	Treatment-related side effects 17 (16.8%) vs 6 (5.7%), P=0.01; early discontinuation 15 vs 3
Pozzi 2013	Azathioprine added, in patients with SCr >2.0 mg/dL	20 vs 26	6 years	Not reported	Not reported	6 (30%) vs 4 (15%) did not complete 12 months
Wang 2013	Cyclophosphamide or mycophenolate mofetil added	20 vs 20 vs 20	12 months	Severe pulmonary infection 8/20 in the mycophenolate arm	As left	2 deaths, both in the mycophenolate arm
Stangou 2011	Azathioprine added	10 vs 12	12 months	Not reported	Respiratory tract infection 5 (50%) vs 7 (58.3%), none requiring hospitalisation	No discontinuation
Min 2017	Leflunomide + low-dose glucocorticoid vs full-dose glucocorticoid	45 vs 40	Median 88 months	Serious adverse events 2 vs 0	Serious pulmonary infection 1 vs 1	Adverse events 13/45 (28.9%) vs 12/40 (30%)

No pooled estimate of any adverse outcome was calculated: definitions, observation periods and denominators were not standardised. In some trials adverse events were more frequent with the glucocorticoid-containing regimen; in others no numerical adverse-event data were reported at all, and the direction of the comparison could not be assessed. These data cover **systemic glucocorticoid regimens only**. They exclude gut-targeted oral budesonide, whose systemic exposure is low, and they do not cover the other drug classes. They therefore cannot represent a complete benefit–risk comparison across treatments.

Table 5C. Safety observations from reports with unresolved adult eligibility. Candidate reports of unresolved adult eligibility. These source safety observations are retained for traceability and are not used as confirmed adult evidence; the basis is recorded in Additional file 3.

Trial	Regimen	Comparator	n	Observation	Serious adverse events	Serious infections	Diabetes / impaired glucose tolerance	Discontinuation for adverse events	Deaths
Pozzi 1999	Methylprednisolone 1 g/d ×3 days at months 1, 3, 5 + prednisone 0.5 mg/kg alternate days ×6 months	Supportive care	43 vs 43	5 years	Not reported	Not reported	1 case, 2 years after treatment	Withdrawals from the study, all causes: 5 vs 7 (causes not classified)	Not reported
Manno 2009	Prednisone 1.0 mg/kg/d ×2 months then tapered, 6 months	Ramipril alone	48 vs 49	Median 5 years	Not reported	Not reported	Not reported	Withdrawals from the study, all causes: 3 vs 3	Not reported