

Supplementary materials

Table S1 Summary of safety findings (safety analysis set, N = 112)

	Budesonide	Mesalazine
	n = 56	n = 56
Patients with any adverse event, n (%)	26 (46)	25 (45)
Patients with serious adverse event, n (%)	3 (5)	1 (2)
Patients with adverse event leading to discontinuation, n (%)	4 (7)	4 (7)
Adverse events occurring in $\geq 5\%$ of patients in any treatment group, n (%)		
Nasopharyngitis	6 (11)	10 (18)
Pharyngitis	0 (0)	3 (5)
Crohn's disease	1 (2)	3 (5)
Vomiting	3 (5)	0 (0)
Headache	3 (5)	0 (0)

Table S2 Clinical chemistry findings (safety analysis set, N = 112)

Variable	Baseline	Week 2	Week 4	Week 8	Week 10	LOCF
Alanine aminotransferase, U/L						
Budesonide	0.36 (0.30)	0.34 (0.26)	0.31 (0.21)	0.32 (0.22)	0.31 (0.22)	0.32 (0.21)
Mesalazine	0.29 (0.17)	0.31 (0.17)	0.31 (0.16)	0.30 (0.18)	0.29 (0.17)	0.30 (0.19)
Alkaline phosphatase, U/L						
Budesonide	4.39 (1.35)	3.98 (1.07)	3.80 (1.00)	3.63 (1.00)	3.86 (1.23)	3.92 (1.22)
Mesalazine	4.42 (1.53)	4.38 (1.29)	4.42 (1.44)	4.25 (1.12)	4.31 (1.13)	4.45 (1.41)
Aspartate aminotransferase, U/L						
Budesonide	0.35 (0.15)	0.30 (0.13)	0.28 (0.11)	0.30 (0.14)	0.31 (0.12)	0.32 (0.13)
Mesalazine	0.30 (0.12)	0.32 (0.14)	0.32 (0.12)	0.32 (0.15)	0.32 (0.15)	0.32 (0.16)
Bilirubin, $\mu\text{mol/L}$						
Budesonide	10.19 (6.43)	10.96 (5.63)	11.07 (6.04)	11.48 (5.56)	11.27 (5.26)	11.41 (6.28)
Mesalazine	9.88 (7.69)	9.20 (6.94)	9.37 (6.08)	10.30 (6.20)	10.23 (6.67)	9.45 (6.22)
C-reactive protein, mg/L						

Budesonide	12.32	7.92	7.01	7.03	13.13	17.36
	(16.70)	(15.16)	(11.64)	(10.45)	(20.99)	(28.73)
Mesalazine	15.67	14.57	14.07	10.13	10.82	13.55
	(17.41)	(18.44)	(16.42)	(13.20)	(12.93)	(15.37)
Cholesterol, mmol/L						
Budesonide	3.98	4.25	4.40	4.52	4.33	4.28
	(0.88)	(0.95)	(0.93)	(1.08)	(0.92)	(0.93)
Mesalazine	3.47	3.53	3.55	3.63	3.60	3.54
	(0.83)	(0.95)	(0.92)	(0.98)	(0.90)	(0.87)
Creatinine, $\mu\text{mol/L}$)						
Budesonide	64.47	64.72	63.46	63.46	64.59	64.69
	(15.67)	(14.62)	(14.36)	(14.42)	(14.89)	(14.25)
Mesalazine	63.85	63.31	63.91	62.12	63.27	63.43
	(13.53)	(12.50)	(13.93)	(14.22)	(14.18)	(13.47)
DHEA-S, $\mu\text{mol/L}$						
Budesonide	3.78	2.63	2.38	2.44	3.10	3.22
	(2.20)	(2.17)	(2.12)	(2.66)	(2.04)	(2.33)
Mesalazine	3.24	2.98	3.24	3.21	3.24	3.16
	(2.15)	(1.98)	(2.12)	(2.21)	(2.18)	(2.16)
Gamma-glutamyltransferase, U/L						
Budesonide	0.42	0.43	0.40	0.38	0.38	0.42
	(0.25)	(0.25)	(0.22)	(0.21)	(0.25)	(0.29)
Mesalazine	0.41	0.42	0.43	0.38	0.42	0.44
	(0.28)	(0.24)	(0.27)	(0.19)	(0.27)	(0.29)
Glucose, mmol/L						

Budesonide	5.14	5.36	5.42	5.59	5.63	5.59
	(0.84)	(1.02)	(1.05)	(2.21)	(1.22)	(1.18)
Mesalazine	5.40	5.46	5.28	5.67	5.74	5.68
	(0.88)	(0.80)	(0.94)	(1.21)	(1.03)	(1.00)
Potassium, mmol/L						
Budesonide	3.99	3.80	3.81	3.86	3.92	3.90
	(0.29)	(0.37)	(0.30)	(0.35)	(0.33)	(0.33)
Mesalazine	3.98	3.97	4.07	4.00	3.99	3.99
	(0.37)	(0.38)	(0.33)	(0.39)	(0.36)	(0.35)
Protein (g/L)						
Budesonide	71.61	70.95	70.83	70.81	70.64	70.65
	(6.28)	(6.70)	(5.80)	(6.40)	(5.76)	(5.86)
Mesalazine	68.89	68.10	68.63	68.81	68.66	69.19
	(7.23)	(6.48)	(6.56)	(7.93)	(7.17)	(7.69)
Sodium, mmol/L						
Budesonide	140.7	141.2	141.3	141.0	140.3	140.4
	(1.8)	(2.1)	(2.1)	(2.5)	(2.0)	(2.0)
Mesalazine	140.5	140.4	140.4	140.8	140.9	140.6
	(2.1)	(2.0)	(2.1)	(2.2)	(2.2)	(2.3)

DHEA = dehydroepiandrosterone sulfate; LOCF = last observation carried forward.

Figure legend

Fig. S1. Patient flow diagram.

