

Additional file 9. The distribution of adverse events during study period of 12 months

	Group A ^a (n = 22)	Group B ^a (n = 24)	Group C ^a (n = 20)	Group D ^a (n = 22)	P-value ^b
Serious adverse events^c					
Pneumonia	1 ^d			1 ^d	0.724
Seizure	1 ^d			2 (1 ^d ,1 ^e)	0.138
Otitis media acute	1 ^d				0.727
Pyrexia		1 ^d			1
Entropion			1 ^e		0.227
Hepatitis viral			1 ^f		0.227
Nasopharyngitis				1 ^f	0.727
Labial frenectomy			1 ^d		0.227
Other adverse events					
Upper respiratory infection	13	16	10	17	0.305
Pharyngitis	4	3	4		0.132
Rhinorrhea	1	1	1		0.894
Influenza		1			1
Sputum increased				1	0.727
Hand-foot mouth disease	1		1		0.472
Pyrexia	3	2	3		0.287
Diarrhoea			1		0.227
Ileus			1		0.227
Gastroenteritis				1	0.727
Pneumonia	1		4	1	0.058
Nausea	1		1	1	0.702
Decreased appetite				1	0.73
Constipation	5	3	7	6	0.353
Urticaria	2				0.17
Herpes infection		1			1
Seizure				2	0.17
Electroencephalogram abnormal		1		1	1
Cough	1				0.727
Abdomen pain		1			1
Chest pain		1			1
Bacteriuria			1		0.227
Hypertrichosis			1		0.227
Blood electrolyte increased			1		0.227
Hypoadosteronism			1		0.227
Mucocutaneous rash	4	2	2		0.217
Skin abrasion		1			1
Dermatitis diaper				1	0.727
Eczema	1		1		0.472
Pruritus		2			0.242
Cellulitis		1		1	1
Dehydration			1	1	0.472

Tachycardia	2			0.17
Tachypnoea	1			0.727
Fatigue	1			0.727
Otitis media acute		1	1	1
Swelling of eyelid	1			0.727
Hordeolum		1		1

^aGroup A (n = 22) received UCB and EPO, group B (n = 24) received UCB and placebo EPO, group C (n = 20) received placebo UCB and EPO, and group D (n = 22) received placebo UCB and placebo EPO. ^bP-values were calculated for difference among four groups of the number of patients with reported adverse events using Fisher's exact analysis. ^cSerious adverse events were defined as any event, resulting in death, life-threatening, requiring hospitalization or prolongation of hospital stay. Relationship with the intervention in serious adverse events were shown as ^dunlikely, ^enon-related or ^fcannot be evaluated.

The source of terminology was Medical Dictionary for Regulatory Activities (MedDRA) 21.1.

