Table: Exacerbations and adverse events

	FCM (N = 24)		Placebo (N = 24)		P value
	No. of subjects (%)	No. of events	No. of subjects (%)	No. of events	
Exacerbations	7 (29.2)	7	7 (29.2)	12	1.00
Use of antibiotics	6 (25.0)	6	5 (20.8)	8	0.73
Use of steroids	5 (20.8)	5	5 (20.8)	6	1.00
Adverse events, all	22 (91.7)	48	17 (70.8)	28	0.14
Hypophosphatemia[1]	22 (91.7)	22	2 (8.3)	2	< 0.001
Other abnormal laboratory tests[2]	8 (33.3)	10	7 (29.2)	8	0.76
Hypertension[3]	5 (20.8)	5	4 (16.7)	4	1.00
Dyspnea	3 (12.5)	3	0	0	0.23
Headache	2 (8.3)	2	4 (16.7)	4	0.67
Hematoma	2 (8.3)	2	2 (8.3)	2	1.00
Fever	1 (4.2)	1	0	0	1.00
Rash	1 (4.2)	1	0	0	1.00
Upper respiratory infection	1 (4.2)	1	0	0	1.00
Cough	1 (4.2)	1	0	0	1.00
Nasal congestion	0	0	1 (4.2)	1	1.00
Lung infection	0	0	1 (4.2)	2	1.00
Vomiting	0	0	1 (4.2)	1	1.00
Diarrhea	0	0	1 (4.2)	1	1.00
Dyspepsia	0	0	1 (4.2)	1	1.00
Dizziness	0	0	1 (4.2)	1	1.00
Fall	0	0	1 (4.2)	1	1.00
Serious adverse events, all	0	0	2 (8.3)	2	0.49
Lung infection, requiring hospitalization	0	0	1 (4.2)	1	1.00
Fall, requiring hospitalization	0	0	1 (4.2)	1	1.00

Adverse events were recorded up to one week post-infusion and coded using the Common Terminology Criteria for Adverse Events (CTCAE). Serious adverse events were recorded for the entire study duration. Preexisting events were not considered adverse events unless they changed in severity (increase by one grade or more) or frequency. The total number of participants with adverse events does not correspond to the sum of numbers of participants with a particular adverse event, as some participants had multiple adverse event. P values were calculated using Chi-square or Fisher's exact tests for differences in numbers of subjects with a given event. FCM: ferric carboxymaltose.

[1] Hypophosphatemia was defined as phosphate levels <0.8 mmol/L. Phosphate levels were routinely measured in only 29 participants during the study (14 of those received FCM). Numbers reported here are based on the retrospective analysis of stored serum samples from all participants.

[2] These included in order of frequency: elevated C-reactive protein, hypoalbuminemia, thrombocytosis, hypokalemia, anemia, hyperkalemia, elevated white cell and neutrophil counts (no significant between-group differences for any of those values).

[3] Hypertension was considered an adverse event if the elevated blood pressure was not preexistent (i.e. the grade of hypertension as defined by CTCAE observed immediately post-infusion or at week 1 was not present on any occasion prior to infusion) or was preexistent but worsened (i.e. an increase by at least one grade as defined by CTCAE immediately post-infusion or at week 1).