Follow-up phase: Laboratory parameters

Haematological

Table 1 gives the mean difference (standard error) of change in haematological laboratory parameters from baseline to each treatment visit for the adalimumab group and for the placebo group. None of the differences were significant at the 5% level. None of the mean changes in haematological assessments were considered to be clinically significant.

Table 1: Mean difference in haematological variables from baseline to each treatment visit of adalimumab compared to placebo

Variable	Mean difference of change from baseline in adalimumab compared to placebo (Standard Error)				
	1 month	2 months	3 months	6 months	9 months
Haematocrit (%)	0.08 (0.71)	-0.21 (0.90)	0.34 (1.56)	1.27 (1.57)	1.65 (1.76)
Haemoglobin (g/dL)	-0.21 (0.36)	2.14 (3.63)	0.18 (0.39)	0.03 (0.43)	0.02 (0.61)
Red blood cell count (10^{12}/L)	-0.00 (0.07)	0.07 (0.07)	0.12 (0.13)	0.20 (0.13)	0.18 (0.11)
White blood cell count (10^{12}/L)	0.17 (0.78)	0.04 (0.54)	1.20 (1.18)	0.63 (0.96)	-0.30 (0.98)
Neutrophils (10^9/L)	-0.12 (0.62)	-0.08 (0.48)	0.94 (0.98)	0.08 (0.71)	-0.85 (0.73)
Lymphocytes (10^9/L)	-0.04 (0.26)	0.02 (0.23)	-0.05 (0.46)	0.23 (0.46)	0.04 (0.39)
Monocytes (10^9/L)	0.10 (0.05)	0.06 (0.05)	0.12 (0.14)	0.06 (0.09)	0.04 (0.10)
Basophils (10^9/L)	0.01 (0.01)	0.01 (0.01)	-0.01 (0.01)	0.02 (0.01)	0.01 (0.01)
Eosinophils (10^9/L)	0.15 (0.09)	0.09 (0.10)	0.12 (0.11)	0.14 (0.14)	0.27 (0.16)
Platelet count (10^9/L)	-17.43 (15.72)	-9.72 (16.63)	-9.95 (24.57)	46.02 (33.41)	-5.33 (26.69)
ESR	-0.15 (3.25)	9.08 (5.85)	4.58 (5.94)	0.13 (3.95)	4.67 (5.54)
Plasma viscosity**	NA	NA	NA	NA	NA

*In the placebo arm there was only 1 assessment done at baseline and at each follow-up visit therefore no mean difference could be calculated between the two groups.

Tables 2-25 show the haematological summary data.

Table 2: Haematocrit Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	17 (70.83%)	5 (20.83%)	1 (20.00%)	1 (20.00%)	2 (8.33%)	0 (0%)
2	22	14 (63.64%)	3 (13.64%)	3 (100.00%)	0 (0%)	5 (22.73%)	0 (0%)
3	10	8 (80.00%)	1 (10.00%)	0 (0%)	1 (100.00%)	1 (10.00%)	0 (0%)
4	9	6 (66.67%)	3 (33.33%)	2 (66.67%)	0 (0%)	0 (0%)	0 (0%)
5	7	3 (42.86%)	2 (28.57%)	2 (100.00%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 3: Haematocrit Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	40 (70.18%)	8 (14.04%)	4 (50.00%)	0 (0%)	9 (15.79%)	0 (0%)
2	52	41 (78.85%)	6 (11.54%)	5 (83.33%)	0 (0%)	5 (9.62%)	0 (0%)
3	18	15 (83.33%)	0 (0%)	0 (0%)	0 (0%)	3 (16.67%)	0 (0%)
4	16	13 (81.25%)	1 (6.25%)	1 (100.00%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	6 (60.00%)	2 (20.00%)	2 (100.00%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	7 (77.78%)	1 (11.11%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 4: Haemoglobin Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	21 (87.50%)	2 (8.33%)	1 (50.00%)	0 (0%)	1 (4.17%)	0 (0%)
2	22	16 (72.73%)	2 (9.09%)	2 (100.00%)	0 (0%)	4 (18.18%)	0 (0%)
3	10	8 (80.00%)	1 (10.00%)	0 (0%)	1 (100.00%)	1 (10.00%)	0 (0%)
4	9	8 (88.89%)	1 (11.11%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 5: Haemoglobin Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	40 (70.18%)	8 (14.04%)	4 (50.00%)	0 (0%)	9 (15.79%)	0 (0%)
2	52	41 (78.85%)	6 (11.54%)	5 (83.33%)	0 (0%)	5 (9.62%)	0 (0%)
3	18	15 (83.33%)	0 (0%)	0 (0%)	0 (0%)	3 (16.67%)	0 (0%)
4	16	13 (81.25%)	1 (6.25%)	1 (100.00%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	6 (60.00%)	2 (20.00%)	2 (100.00%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	7 (77.78%)	1 (11.11%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 6: Red blood cell count Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	23 (95.83%)	0 (0%)	0 (0%)	0 (0%)	1 (4.17%)	0 (0%)
2	22	17 (77.27%)	1 (4.55%)	1 (100.00%)	0 (0%)	4 (18.18%)	0 (0%)
3	10	8 (80.00%)	1 (10.00%)	1 (100.00%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	3 (50.00%)	2 (33.33%)	1 (50.00%)	0 (0%)	1 (16.67%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 7: Red blood cell count Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	48 (84.21%)	4 (7.02%)	2 (50.00%)	0 (0%)	5 (8.77%)	0 (0%)
2	52	46 (88.46%)	3 (5.77%)	2 (66.67%)	0 (0%)	3 (5.77%)	0 (0%)
3	18	17 (94.44%)	0 (0%)	0 (0%)	0 (0%)	1 (5.56%)	0 (0%)
4	16	14 (87.50%)	0 (0%)	0 (0%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	7 (77.78%)	1 (11.11%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 8: White blood cell count Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	21 (87.50%)	2 (8.33%)	0 (0%)	1 (50.00%)	1 (4.17%)	0 (0%)
2	22	17 (77.27%)	1 (4.55%)	0 (0%)	0 (0%)	4 (18.18%)	0 (0%)
3	10	9 (90.00%)	0 (0%)	0 (0%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 9: White blood cell count Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	47 (82.46%)	5 (8.77%)	0 (0%)	0 (0%)	5 (8.77%)	0 (0%)
2	52	45 (86.54%)	4 (7.69%)	1 (25.00%)	0 (0%)	3 (5.77%)	0 (0%)
3	18	15 (83.33%)	2 (11.11%)	1 (50.00%)	0 (0%)	1 (5.56%)	0 (0%)
4	16	13 (81.25%)	1 (6.25%)	1 (100.00%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	7 (70.00%)	1 (10.00%)	1 (100.00%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 10: Neutrophils Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	21 (87.50%)	2 (8.33%)	0 (0%)	1 (50.00%)	1 (4.17%)	0 (0%)
2	22	18 (81.82%)	0 (0%)	0 (0%)	0 (0%)	4 (18.18%)	0 (0%)
3	10	8 (80.00%)	1 (10.00%)	0 (0%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 11: Neutrophils Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	46 (80.70%)	6 (10.53%)	1 (16.67%)	0 (0%)	5 (8.77%)	0 (0%)
2	52	45 (86.54%)	4 (7.69%)	1 (25.00%)	0 (0%)	3 (5.77%)	0 (0%)
3	18	15 (83.33%)	2 (11.11%)	1 (50.00%)	0 (0%)	1 (5.56%)	0 (0%)
4	16	14 (87.50%)	0 (0%)	0 (0%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	7 (70.00%)	1 (10.00%)	1 (100.00%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 12: Lymphocytes Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	23 (95.83%)	0 (0%)	0 (0%)	0 (0%)	1 (4.17%)	0 (0%)
2	22	18 (81.82%)	0 (0%)	0 (0%)	0 (0%)	4 (18.18%)	0 (0%)
3	10	9 (90.00%)	0 (0%)	0 (0%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 13: Lymphocytes Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	50 (87.72%)	2 (3.51%)	0 (0%)	0 (0%)	5 (8.77%)	0 (0%)
2	52	47 (90.38%)	2 (3.85%)	1 (50.00%)	0 (0%)	3 (5.77%)	0 (0%)
3	18	15 (83.33%)	2 (11.11%)	1 (50.00%)	0 (0%)	1 (5.56%)	0 (0%)
4	16	13 (81.25%)	1 (6.25%)	1 (100.00%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	8 (88.89%)	0 (0%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 14: Monocytes Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	21 (87.50%)	2 (8.33%)	2 (100.00%)	0 (0%)	1 (4.17%)	0 (0%)
2	22	17 (77.27%)	1 (4.55%)	1 (100.00%)	0 (0%)	4 (18.18%)	0 (0%)
3	10	9 (90.00%)	0 (0%)	0 (0%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 15: Monocytes Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	51 (89.47%)	1 (1.75%)	1 (100.00%)	0 (0%)	5 (8.77%)	0 (0%)
2	52	49 (94.23%)	0 (0%)	0 (0%)	0 (0%)	3 (5.77%)	0 (0%)
3	18	14 (77.78%)	3 (16.67%)	0 (0%)	0 (0%)	1 (5.56%)	0 (0%)
4	16	14 (87.50%)	0 (0%)	0 (0%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	8 (88.89%)	0 (0%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 16: Basophils Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	22 (91.67%)	1 (4.17%)	1 (100.00%)	0 (0%)	1 (4.17%)	0 (0%)
2	22	18 (81.82%)	0 (0%)	0 (0%)	0 (0%)	4 (18.18%)	0 (0%)
3	10	7 (70.00%)	2 (20.00%)	1 (50.00%)	1 (50.00%)	1 (10.00%)	0 (0%)
4	9	8 (88.89%)	1 (11.11%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
5	7	4 (57.14%)	1 (14.29%)	1 (100.00%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 17: Basophils Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	52 (91.23%)	0 (0%)	0 (0%)	0 (0%)	5 (8.77%)	0 (0%)
2	52	47 (90.38%)	1 (1.92%)	0 (0%)	0 (0%)	4 (7.69%)	0 (0%)
3	18	17 (94.44%)	0 (0%)	0 (0%)	0 (0%)	1 (5.56%)	0 (0%)
4	16	14 (87.50%)	0 (0%)	0 (0%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	8 (88.89%)	0 (0%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 18: Eosinophils Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	22 (91.67%)	1 (4.17%)	0 (0%)	0 (0%)	1 (4.17%)	0 (0%)
2	22	17 (77.27%)	1 (4.55%)	0 (0%)	0 (0%)	4 (18.18%)	0 (0%)
3	10	9 (90.00%)	0 (0%)	0 (0%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 19: Eosinophils Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	48 (84.21%)	4 (7.02%)	1 (25.00%)	1 (25.00%)	5 (8.77%)	0 (0%)
2	52	43 (82.69%)	5 (9.62%)	3 (60.00%)	0 (0%)	4 (7.69%)	0 (0%)
3	18	16 (88.89%)	1 (5.56%)	1 (100.00%)	0 (0%)	1 (5.56%)	0 (0%)
4	16	13 (81.25%)	1 (6.25%)	1 (100.00%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	7 (77.78%)	1 (11.11%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 20: Platelet count Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	22 (91.67%)	1 (4.17%)	1 (100.00%)	0 (0%)	1 (4.17%)	0 (0%)
2	22	15 (68.18%)	3 (13.64%)	2 (66.67%)	1 (33.33%)	4 (18.18%)	0 (0%)
3	10	8 (80.00%)	1 (10.00%)	0 (0%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	4 (57.14%)	1 (14.29%)	1 (100.00%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 21: Platelet count Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	46 (80.70%)	5 (8.77%)	3 (60.00%)	0 (0%)	6 (10.53%)	0 (0%)
2	52	43 (82.69%)	6 (11.54%)	3 (50.00%)	1 (16.67%)	3 (5.77%)	0 (0%)
3	18	16 (88.89%)	0 (0%)	0 (0%)	0 (0%)	2 (11.11%)	0 (0%)
4	16	14 (87.50%)	0 (0%)	0 (0%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	7 (70.00%)	1 (10.00%)	1 (100.00%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 22: Erythrocyte sedimentation rate Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	14 (58.33%)	5 (20.83%)	4 (80.00%)	3 (60.00%)	5 (20.83%)	0 (0%)
2	22	11 (50.00%)	3 (13.64%)	2 (66.67%)	1 (33.33%)	8 (36.36%)	0 (0%)
3	10	5 (50.00%)	3 (30.00%)	2 (66.67%)	1 (33.33%)	2 (20.00%)	0 (0%)
4	9	6 (66.67%)	2 (22.22%)	2 (100.00%)	0 (0%)	1 (11.11%)	0 (0%)
5	7	3 (42.86%)	1 (14.29%)	1 (100.00%)	0 (0%)	3 (42.86%)	0 (0%)
6	6	4 (66.67%)	0 (0%)	0 (0%)	0 (0%)	2 (33.33%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 23: Erythrocyte sedimentation rate Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	30 (52.63%)	14 (24.56%)	11 (78.57%)	2 (14.29%)	13 (22.81%)	0 (0%)
2	52	29 (55.77%)	12 (23.08%)	9 (75.00%)	2 (16.67%)	9 (17.31%)	2 (3.85%)
3	18	9 (50.00%)	6 (33.33%)	5 (83.33%)	2 (33.33%)	3 (16.67%)	0 (0%)
4	16	10 (62.50%)	3 (18.75%)	3 (100.00%)	0 (0%)	3 (18.75%)	0 (0%)
5	10	6 (60.00%)	2 (20.00%)	1 (50.00%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	6 (66.67%)	1 (11.11%)	1 (100.00%)	0 (0%)	2 (22.22%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 24: Plasma viscosity Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	0 (0%)	0 (0%)	0 (0%)	0 (0%)	5 (20.83%)	19 (79.17%)
2	22	0 (0%)	0 (0%)	0 (0%)	0 (0%)	8 (36.36%)	14 (63.64%)
3	10	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	8 (80.00%)
4	9	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (11.11%)	8 (88.89%)
5	7	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (42.86%)	4 (57.14%)
6	6	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (33.33%)	4 (66.67%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 25: Plasma viscosity Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	2 (3.51%)	0 (0%)	0 (0%)	0 (0%)	11 (19.30%)	44 (77.19%)
2	52	2 (3.85%)	0 (0%)	0 (0%)	0 (0%)	6 (11.54%)	44 (84.62%)
3	18	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (16.67%)	15 (83.33%)
4	16	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (18.75%)	13 (81.25%)
5	10	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	8 (80.00%)
6	9	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (22.22%)	7 (77.78%)

*Assessment missing but not recorded as 'Not done' on CRF

Biochemical Assessments

Table 26 gives the mean difference (standard error) of change in biochemical laboratory parameters from baseline to each treatment visit for the adalimumab group and for the placebo group. Differences marked by an asterisk were significant at the 5% level. None of the mean changes in biochemical assessments were considered to be clinically significant.

Table 26: Mean difference (standard error) in biochemical variables from baseline to each treatment visit of adalimumab compared to placebo

Variable	1 month	2 months	3 months	6 months	9 months
CRP (mg/L)	4.88 (2.64)	2.97 (2.06)	12.21 (14.61)	6.42 (3.88)	-11.41 (11.59)
Urea (mmol/L)	-0.51 (0.27)	-0.37 (0.36)	-0.36 (0.40)	-0.89 (0.43)*	0.52 (0.43)
Creatinine (mmol/L)	-5.06 (4.56)	-2.16 (3.98)	8.91 (9.06)	11.89 (8.77)	12.84 (7.98)
Sodium (mmol/L)	0.41 (0.68)	0.14 (0.75)	0.73 (1.05)	0.92 (1.01)	1.28 (1.56)
Potassium (mmol/L)	0.05 (0.12)	0.11 (0.10)	-0.49 (0.12)*	-0.25 (0.15)	-0.34 (0.18)
Calcium (mmol/L)	0.00 (0.03)	-0.01 (0.03)	0.06 (0.05)	0.08 (0.06)	0.11 (0.10)
Inorganic phosphate (mmol/L)	0.05 (0.06)	-0.02 (0.07)	0.01 (0.12)	0.02 (0.09)	0.21 (0.09)*
Glucose (mmol/L)	-0.10 (0.31)	0.01 (0.34)	0.13 (0.47)	-0.21 (0.35)	-0.32 (0.37)
Chloride (mmol/L)	-0.88 (0.83)	0.05 (0.78)	0.33 (0.96)	-0.64 (1.11)	-1.50 (1.74)
Bicarbonate (mmol/L)	0.72 (0.94)	0.31 (1.14)	1.25 (2.00)	-0.38 (1.63)	2.78 (2.59)
Total bilirubin (mmol/L)	-0.01 (1.07)	1.72 (1.25)	1.11 (2.47)	1.26 (1.78)	1.49 (1.09)
ALT (iu/L)	15.84 (13.00)	-1.40 (10.46)	11.83 (17.28)	10.12 (7.42)	7.60 (10.75)
AST (iu/L)	6.25 (5.54)	-0.22 (7.62)	1.92 (7.10)	1.47 (2.89)	-0.21 (2.44)

Tables 27-52 show the biochemical summary data

Table 27: C-Reactive Protein Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	20 (83.33%)	3 (12.50%)	2 (66.67%)	1 (33.33%)	1 (4.17%)	0 (0%)
2	22	16 (72.73%)	2 (9.09%)	2 (100.00%)	0 (0%)	4 (18.18%)	0 (0%)
3	10	7 (70.00%)	2 (20.00%)	1 (50.00%)	1 (50.00%)	1 (10.00%)	0 (0%)
4	9	7 (77.78%)	2 (22.22%)	2 (100.00%)	0 (0%)	0 (0%)	0 (0%)
5	7	2 (28.57%)	2 (28.57%)	2 (100.00%)	0 (0%)	3 (42.86%)	0 (0%)
6	6	4 (66.67%)	1 (16.67%)	0 (0%)	1 (100.00%)	1 (16.67%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 28: C-Reactive Protein Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	46 (80.70%)	4 (7.02%)	1 (25.00%)	0 (0%)	7 (12.28%)	0 (0%)
2	52	44 (84.62%)	3 (5.77%)	2 (66.67%)	0 (0%)	4 (7.69%)	1 (1.92%)
3	18	15 (83.33%)	2 (11.11%)	0 (0%)	1 (50.00%)	1 (5.56%)	0 (0%)
4	16	12 (75.00%)	2 (12.50%)	2 (100.00%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	6 (60.00%)	2 (20.00%)	2 (100.00%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 29: Urea Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	22 (91.67%)	1 (4.17%)	0 (0%)	0 (0%)	1 (4.17%)	0 (0%)
2	22	17 (77.27%)	1 (4.55%)	0 (0%)	0 (0%)	4 (18.18%)	0 (0%)
3	10	9 (90.00%)	0 (0%)	0 (0%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	8 (88.89%)	1 (11.11%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 30: Urea Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	49 (85.96%)	3 (5.26%)	2 (66.67%)	0 (0%)	5 (8.77%)	0 (0%)
2	52	45 (86.54%)	3 (5.77%)	1 (33.33%)	0 (0%)	3 (5.77%)	1 (1.92%)
3	18	17 (94.44%)	0 (0%)	0 (0%)	0 (0%)	1 (5.56%)	0 (0%)
4	16	13 (81.25%)	1 (6.25%)	1 (100.00%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 31: Creatinine Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	20 (83.33%)	3 (12.50%)	2 (66.67%)	0 (0%)	1 (4.17%)	0 (0%)
2	22	16 (72.73%)	2 (9.09%)	2 (66.67%)	0 (0%)	4 (18.18%)	0 (0%)
3	10	9 (90.00%)	0 (0%)	0 (0%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	5 (83.33%)	1 (16.67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 32: Creatinine Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	47 (82.46%)	6 (10.53%)	2 (33.33%)	0 (0%)	4 (7.02%)	0 (0%)
2	52	46 (88.46%)	3 (5.77%)	0 (0%)	0 (0%)	3 (5.77%)	0 (0%)
3	18	16 (88.89%)	1 (5.56%)	0 (0%)	0 (0%)	1 (5.56%)	0 (0%)
4	16	14 (87.50%)	0 (0%)	0 (0%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 33: Sodium Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	23 (95.83%)	0 (0%)	0 (0%)	0 (0%)	1 (4.17%)	0 (0%)
2	22	19 (86.36%)	0 (0%)	0 (0%)	0 (0%)	3 (13.64%)	0 (0%)
3	10	9 (90.00%)	0 (0%)	0 (0%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 34: Sodium Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	53 (92.98%)	0 (0%)	0 (0%)	0 (0%)	4 (7.02%)	0 (0%)
2	52	49 (94.23%)	0 (0%)	0 (0%)	0 (0%)	3 (5.77%)	0 (0%)
3	18	14 (77.78%)	3 (16.67%)	1 (33.33%)	0 (0%)	1 (5.56%)	0 (0%)
4	16	13 (81.25%)	1 (6.25%)	0 (0%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 35: Potassium Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	21 (87.50%)	1 (4.17%)	0 (0%)	0 (0%)	2 (8.33%)	0 (0%)
2	22	19 (86.36%)	0 (0%)	0 (0%)	0 (0%)	3 (13.64%)	0 (0%)
3	10	9 (90.00%)	0 (0%)	0 (0%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 36: Potassium Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	47 (82.46%)	3 (5.26%)	3 (100.00%)	0 (0%)	7 (12.28%)	0 (0%)
2	52	48 (92.31%)	0 (0%)	0 (0%)	0 (0%)	4 (7.69%)	0 (0%)
3	18	16 (88.89%)	1 (5.56%)	0 (0%)	0 (0%)	1 (5.56%)	0 (0%)
4	16	14 (87.50%)	0 (0%)	0 (0%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	7 (77.78%)	0 (0%)	0 (0%)	0 (0%)	2 (22.22%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 37: Calcium Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	15 (62.50%)	1 (4.17%)	0 (0%)	0 (0%)	8 (33.33%)	0 (0%)
2	22	16 (72.73%)	0 (0%)	0 (0%)	0 (0%)	6 (27.27%)	0 (0%)
3	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	4 (66.67%)	0 (0%)	0 (0%)	0 (0%)	2 (33.33%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 38: Calcium Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	42 (73.68%)	0 (0%)	0 (0%)	0 (0%)	15 (26.32%)	0 (0%)
2	52	43 (82.69%)	0 (0%)	0 (0%)	0 (0%)	9 (17.31%)	0 (0%)
3	18	15 (83.33%)	0 (0%)	0 (0%)	0 (0%)	3 (16.67%)	0 (0%)
4	16	13 (81.25%)	0 (0%)	0 (0%)	0 (0%)	3 (18.75%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	8 (88.89%)	0 (0%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 39: Inorganic phosphate Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	15 (62.50%)	0 (0%)	0 (0%)	0 (0%)	9 (37.50%)	0 (0%)
2	22	15 (68.18%)	1 (4.55%)	0 (0%)	0 (0%)	6 (27.27%)	0 (0%)
3	10	7 (70.00%)	1 (10.00%)	0 (0%)	1 (100.00%)	2 (20.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	4 (57.14%)	1 (14.29%)	1 (100.00%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	5 (83.33%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 40: Inorganic phosphate Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	37 (64.91%)	5 (8.77%)	3 (60.00%)	0 (0%)	15 (26.32%)	0 (0%)
2	52	37 (71.15%)	4 (7.69%)	1 (25.00%)	0 (0%)	11 (21.15%)	0 (0%)
3	18	13 (72.22%)	2 (11.11%)	0 (0%)	0 (0%)	3 (16.67%)	0 (0%)
4	16	13 (81.25%)	1 (6.25%)	0 (0%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	7 (70.00%)	1 (10.00%)	1 (100.00%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	8 (88.89%)	0 (0%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 41: Glucose Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	14 (58.33%)	2 (8.33%)	0 (0%)	0 (0%)	8 (33.33%)	0 (0%)
2	22	15 (68.18%)	0 (0%)	0 (0%)	0 (0%)	7 (31.82%)	0 (0%)
3	10	7 (70.00%)	1 (10.00%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
4	9	8 (88.89%)	0 (0%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	3 (50.00%)	0 (0%)	0 (0%)	0 (0%)	3 (50.00%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 42: Glucose Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	41 (71.93%)	3 (5.26%)	1 (33.33%)	0 (0%)	13 (22.81%)	0 (0%)
2	52	42 (80.77%)	2 (3.85%)	0 (0%)	0 (0%)	8 (15.38%)	0 (0%)
3	18	12 (66.67%)	2 (11.11%)	0 (0%)	0 (0%)	4 (22.22%)	0 (0%)
4	16	13 (81.25%)	0 (0%)	0 (0%)	0 (0%)	3 (18.75%)	0 (0%)
5	10	7 (70.00%)	0 (0%)	0 (0%)	0 (0%)	3 (30.00%)	0 (0%)
6	9	8 (88.89%)	0 (0%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 43: Chloride Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	20 (83.33%)	0 (0%)	0 (0%)	0 (0%)	4 (16.67%)	0 (0%)
2	22	14 (63.64%)	2 (9.09%)	0 (0%)	0 (0%)	6 (27.27%)	0 (0%)
3	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
4	9	7 (77.78%)	1 (11.11%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	3 (50.00%)	0 (0%)	0 (0%)	0 (0%)	3 (50.00%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 44: Chloride Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	42 (73.68%)	3 (5.26%)	1 (33.33%)	0 (0%)	12 (21.05%)	0 (0%)
2	52	43 (82.69%)	1 (1.92%)	0 (0%)	0 (0%)	8 (15.38%)	0 (0%)
3	18	14 (77.78%)	1 (5.56%)	0 (0%)	0 (0%)	3 (16.67%)	0 (0%)
4	16	13 (81.25%)	0 (0%)	0 (0%)	0 (0%)	3 (18.75%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	8 (88.89%)	0 (0%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 45: Bicarbonate Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	11 (45.83%)	2 (8.33%)	0 (0%)	0 (0%)	11 (45.83%)	0 (0%)
2	22	10 (45.45%)	1 (4.55%)	0 (0%)	0 (0%)	11 (50.00%)	0 (0%)
3	10	6 (60.00%)	2 (20.00%)	2 (100.00%)	0 (0%)	2 (20.00%)	0 (0%)
4	9	7 (77.78%)	1 (11.11%)	1 (100.00%)	0 (0%)	1 (11.11%)	0 (0%)
5	7	4 (57.14%)	1 (14.29%)	1 (100.00%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	2 (33.33%)	1 (16.67%)	1 (100.00%)	0 (0%)	3 (50.00%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 46: Bicarbonate Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	28 (49.12%)	6 (10.53%)	4 (66.67%)	0 (0%)	23 (40.35%)	0 (0%)
2	52	29 (55.77%)	7 (13.46%)	4 (57.14%)	0 (0%)	16 (30.77%)	0 (0%)
3	18	11 (61.11%)	1 (5.56%)	1 (100.00%)	0 (0%)	6 (33.33%)	0 (0%)
4	16	7 (43.75%)	3 (18.75%)	3 (100.00%)	0 (0%)	6 (37.50%)	0 (0%)
5	10	6 (60.00%)	1 (10.00%)	1 (100.00%)	0 (0%)	3 (30.00%)	0 (0%)
6	9	7 (77.78%)	0 (0%)	0 (0%)	0 (0%)	2 (22.22%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 47: Total bilirubin Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	19 (79.17%)	1 (4.17%)	0 (0%)	1 (100.00%)	4 (16.67%)	0 (0%)
2	22	19 (86.36%)	0 (0%)	0 (0%)	0 (0%)	3 (13.64%)	0 (0%)
3	10	8 (80.00%)	1 (10.00%)	0 (0%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	9 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	5 (83.33%)	1 (16.67%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 48: Total bilirubin Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	50 (87.72%)	1 (1.75%)	1 (100.00%)	0 (0%)	6 (10.53%)	0 (0%)
2	52	49 (94.23%)	0 (0%)	0 (0%)	0 (0%)	3 (5.77%)	0 (0%)
3	18	17 (94.44%)	0 (0%)	0 (0%)	0 (0%)	1 (5.56%)	0 (0%)
4	16	13 (81.25%)	1 (6.25%)	1 (100.00%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	8 (88.89%)	0 (0%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 49: Alanine aminotransferase Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	19 (79.17%)	2 (8.33%)	0 (0%)	1 (50.00%)	3 (12.50%)	0 (0%)
2	22	18 (81.82%)	1 (4.55%)	1 (100.00%)	0 (0%)	3 (13.64%)	0 (0%)
3	10	8 (80.00%)	1 (10.00%)	1 (100.00%)	0 (0%)	1 (10.00%)	0 (0%)
4	9	8 (88.89%)	1 (11.11%)	1 (100.00%)	0 (0%)	0 (0%)	0 (0%)
5	7	5 (71.43%)	0 (0%)	0 (0%)	0 (0%)	2 (28.57%)	0 (0%)
6	6	6 (100.00%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 50: Alanine aminotransferase Assessments – Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	42 (73.68%)	10 (17.54%)	3 (30.00%)	4 (40.00%)	5 (8.77%)	0 (0%)
2	52	43 (82.69%)	4 (7.69%)	2 (50.00%)	1 (25.00%)	5 (9.62%)	0 (0%)
3	18	16 (88.89%)	1 (5.56%)	0 (0%)	1 (100.00%)	1 (5.56%)	0 (0%)
4	16	12 (75.00%)	2 (12.50%)	2 (100.00%)	0 (0%)	2 (12.50%)	0 (0%)
5	10	8 (80.00%)	0 (0%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	8 (88.89%)	1 (11.11%)	0 (0%)	1 (100.00%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 51: Aspartate aminotransferase Assessments – Placebo

Follow up Visit	Placebo						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	24	12 (50.00%)	1 (4.17%)	1 (100.00%)	0 (0%)	11 (45.83%)	0 (0%)
2	22	9 (40.91%)	1 (4.55%)	1 (100.00%)	0 (0%)	12 (54.55%)	0 (0%)
3	10	7 (70.00%)	1 (10.00%)	1 (100.00%)	0 (0%)	2 (20.00%)	0 (0%)
4	9	8 (88.89%)	0 (0%)	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)
5	7	4 (57.14%)	0 (0%)	0 (0%)	0 (0%)	3 (42.86%)	0 (0%)
6	6	3 (50.00%)	0 (0%)	0 (0%)	0 (0%)	3 (50.00%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Table 52: Aspartate aminotransferase Assessments - Adalimumab

Follow up Visit	Adalimumab						
	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number expected, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not done, N (%)	Missing*, N (%)
1	57	34 (59.65%)	5 (8.77%)	1 (20.00%)	1 (20.00%)	18 (31.58%)	0 (0%)
2	52	34 (65.38%)	6 (11.54%)	1 (16.67%)	2 (33.33%)	11 (21.15%)	1 (1.92%)
3	18	12 (66.67%)	2 (11.11%)	1 (50.00%)	1 (50.00%)	3 (16.67%)	1 (5.56%)
4	16	10 (62.50%)	2 (12.50%)	2 (100.00%)	0 (0%)	4 (25.00%)	0 (0%)
5	10	7 (70.00%)	1 (10.00%)	0 (0%)	0 (0%)	2 (20.00%)	0 (0%)
6	9	6 (66.67%)	1 (11.11%)	1 (100.00%)	0 (0%)	2 (22.22%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF

Urinalysis

Table 53 shows the number of abnormal urinalysis assessments in each treatment group over time. Details on the microscopic analysis are presented in Table 54. Overall the results from the urinalysis were not clinically significant.

Table 53: Number of abnormal urinalysis assessments at each visit

Follow up Visit	Allocation	Number of abnormal assessments (number of participants)
1	Adalimumab	19 (12)
	Placebo	9 (5)
2	Adalimumab	7 (6)
	Placebo	10 (7)
3	Adalimumab	6 (4)
	Placebo	6 (3)
4	Adalimumab	5 (5)
	Placebo	3 (3)
5	Adalimumab	2 (2)
	Placebo	4 (3)
6	Adalimumab	1 (1)
	Placebo	3 (2)

Table 54: Microscopic Urinalysis results

Follow-up Visit	Allocation	Number of assessments, N	Normal assessments, N (%)	Abnormal Assessment, N (%)	If abnormal, number of clinically significant, N (%)	Assessment recorded as not applicable, N (%)	Missing*, N (%)
1	Adalimumab	12	5 (41.67%)	5 (41.67%)	2 (40.00%)	2 (16.67%)	0 (0%)
	Placebo	5	1 (20.00%)	4 (80.00%)	1 (25.00%)	0 (0%)	0 (0%)
2	Adalimumab	6	4 (66.67%)	2 (33.33%)	0 (0%)	0 (0%)	0 (0%)
	Placebo	7	4 (57.14%)	3 (42.86%)	1 (33.33%)	0 (0%)	0 (0%)
3	Adalimumab	4	3 (75.00%)	0 (0%)	N/A	1 (25.00%)	0 (0%)
	Placebo	3	1 (33.33%)	1 (33.33%)	1 (100.00%)	0 (0%)	1 (33.33%)
4	Adalimumab	5	4 (80.00%)	0 (0%)	N/A	1 (20.00%)	0 (0%)
	Placebo	3	2 (66.67%)	1 (33.33%)	1 (100.00%)	0 (0%)	0 (0%)
5	Adalimumab	2	2 (100.00%)	0 (0%)	N/A	0 (0%)	0 (0%)
	Placebo	3	1 (33.33%)	2 (66.67%)	2 (100.00%)	0 (0%)	0 (0%)
6	Adalimumab	1	1 (100.00%)	0 (0%)	N/A	0 (0%)	0 (0%)
	Placebo	2	0 (0%)	2 (100.00%)	1 (50.00%)	0 (0%)	0 (0%)

*Assessment missing but not recorded as 'Not done' on CRF