CNS Side Effects

CNS conditions using the grading according to the AIDS Clinical Trial Group (ACTG) Grading Scale (Dec 2004)
Missing data coded as none while patients who dropped out were coded as having no results

CNS side effects		Baseline	Week 4	Week 12	Week 24
0=none 1=mild 2=moderate 3=severe	Attended DNA Drop out	41 0 0	40 0 1	39 0 2	37 2 2
Total CNS score *Max possible=100 (severe)* *Min possible=0 (none)*	Median(IQR	10(3 to 23) Range: 0 to 47	N=40 7(3 to 13) Range: 0 to 40	N=39 10(3 to 17) Range: 0 to 37	N=37 7(3 to 17) Range: 0 to 40
			Baseline to week 4	**Baseline to week 12**	
% improvement in total CNS score from Baseline *(-ve values indicate deterioration)*	Median change (IQR		0(0 to 7) Range: -14 to 34 P=0.028 *Using Wilcoxon signed rank test*	3(0 to 7) Range: -23 to 37 P=0.064 *Using Wilcoxon signed rank test*	0(-2 to 7) Range: -14 to 37 P=0.152 *Using Wilcoxon signed rank test*
Proportion CNS score (moderate & severe)	None mod+severe	27(65.9) 14(34.2)	33(82.5) 7(17.5)	30(76.9) 9(23.1)	27(73.0) 10(27.0)
Total CNS score *Max possible=100 (severe)* *Min possible=0(none/mild)*	Median(IQR	0(0 to 10) Range: 0 to 30	N=40 0(0 to 0) Range: 0 to 25	N=39 0(0 to 0) Range: 0 to 25	N=37 0(0 to 5) Range: 0 to 20

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CNS side effects		Baseline	Week 4	Week 12	Week 24
0=none 1=mild 2=moderate 3=severe	Attended DNA Drop out	41 0 0	40 0 1	39 0 2	37 2 2
			Baseline to week 4	Baseline to week 12	Baseline to week 24
% improvement in total CNS score from Baseline *(-ve values indicate deterioration)*	Median change (IQR		N=40 0(0 to 0) Range: -10 to 30 P=0.064 *Using Wilcoxon signed rank test*	N=39 0(0 to 5) Range: -5 to 30 P=0.022 *Using Wilcoxon signed rank test*	N=37 0(0 to 0) Range: -5 to 30 P=0.081 *Using Wilcoxon signed rank test*
Dizziness	None Mild Moderate Severe	31(75.6) 7(17.1) 3(7.3) 0(0.0)	38(95.0) 1(2.5) 1(2.5) 0(0.0)	34(87.2) 4(10.3) 1(2.6) 0(0.0)	32(86.5) 5(13.5) 0(0.0) 0(0.0)
Dizziness *Categorised none+mild Mod+severe Comparison with baseline*	No change Base None/Mild to Mod/Severe Base Mod/Severe to None/Mild		38(95.0) 0(0.0) 2(5.0)	37(94.9) 0(0.0) 2(5.1)	34(91.9) 0(0.0) 3(8.1)
Dizziness *Comparison with baseline*			McNemars χ^2 result P=0.157	McNemars χ^2 result P=0.157	McNemars χ^2 result P=0.125
Dizziness (binary)	None Mild-Severe	31(75.6) 10(24.4)	38(95.0) 2(5.0)	34(87.2) 5(12.8)	32(86.5) 5(13.5)
Dizziness *Categorised none Mild+Mod+severe Comparison with baseline*	No change Base None to Mild/Mod/Severe Base Mild/Mod/Severe to None		32(80.0) 0(0.0) 8(20.0)	30(76.9) 2(5.1) 7(17.9)	31(83.8) 1(2.7) 5(13.5)
Dizziness (binary) *Comparison with baseline*			McNemars χ^2 result P=0.005	McNemars χ^2 result P=0.096	McNemars χ^2 result P=0.103

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CNS side effects		Baseline	Week 4	Week 12	Week 24
0=none 1=mild 2=moderate 3=severe	Attended DNA Drop out	41 0 0	40 0 1	39 0 2	37 2 2
Depression/low mood	None Mild Moderate Severe	27(65.9) 11(26.8) 3(7.3) 0(0.0)	26(65.0) 13(32.5) 1(2.5) 0(0.0)	23(59.0) 13(33.3) 3(7.7) 0(0.0)	20(54.1) 15(40.5) 2(5.4) 0(0.0)
Depression/low mood *Categorised none+mild* *Mod+severe* *Comparison with baseline*	No change Base None/Mild to Mod/Severe Base Mod/Severe to None/Mild		38(95.0) 0(0.0) 2(5.0)	35(89.7) 2(5.1) 2(5.1)	36(97.3) 0(0.0) 1(2.7)
Depression/low mood *Comparison with baseline*			McNemars χ^2 result P=0.157	McNemars χ^2 result P=0.999	McNemars χ^2 result P=0.317
Depression/low mood (binary)	None Mild-Severe	27(65.9) 14(34.2)	26(65.0) 14(35.0)	23(59.0) 16(41.0)	20(54.1) 17(46.0)
Depression/low mood *Categorised none* *mild+Mod+severe* *Comparison with baseline*	No change Base None to Mild/Mod/Severe Base Mild/Mod/Severe to None		35(87.5) 3(7.5) 2(5.0)	32(82.1) 5(12.8) 2(5.1)	33(89.2) 4(10.8) 0(0.0)
Depression/low mood (binary) *Comparison with baseline*			McNemars χ^2 result P=0.655	McNemars χ^2 result P=0.257	McNemars χ^2 result P=0.046
Insomnia/sleeplessness	None Mild Moderate Severe	18(43.9) 18(43.9) 4(9.8) 1(2.4)	25(62.5) 11(27.5) 3(7.5) 1(2.5)	24(61.5) 10(25.6) 5(12.8) 0(0.0)	18(48.7) 13(35.1) 5(13.5) 1(2.7)
Insomnia/sleeplessness *Categorised none+mild* *Mod+severe* *Comparison with baseline*	No change Base None/Mild to Mod/Severe Base Mod/Severe to None/Mild		37(92.5) 1(2.5) 2(5.0)	35(89.7) 2(5.1) 2(5.1)	33(89.2) 3(8.1) 1(2.7)

CNS side effects		Baseline	Week 4	Week 12	Week 24
0=none *1=mild* *2=moderate* *3=severe*	Attended DNA Drop out	41 0 0	40 0 1	39 0 2	37 2 2
Insomnia/sleeplessness *Comparison with baseline*			McNemars χ^2 result P<=0.564	McNemars χ^2 result P=0.999	McNemars χ^2 result P=0.317
Insomnia/sleeplessness (binary)	None Mild-Severe	18(43.9) 23(56.1)	25(62.5) 15(37.5)	24(61.5) 15(38.5)	18(48.7) 19(51.4)
Insomnia/sleeplessness *Categorised none* *Mild+Mod+severe* *Comparison with baseline*		No change Base None to Mild/Mod/Severe Base Mild/Mod/Severe to None	27(67.5) 3(7.5) 10(25.0)	23(59.0) 5(12.8) 11(28.2)	28(75.7) 4(10.8) 5(13.5)
Insomnia/sleeplessness (binary) *Comparison with baseline*			McNemars χ^2 result P=0.052	McNemars χ^2 result P=0.134	McNemars χ^2 result P=0.739
Anxiety/nervousness	None Mild Moderate Severe	27(65.9) 11(26.8) 3(7.3) 0(0.0)	28(70.0) 11(27.5) 1(2.5) 0(0.0)	23(59.0) 16(41.0) 0(0.0) 0(0.0)	22(59.5) 13(35.1) 2(5.4) 0(0.0)
Anxiety/nervousness *Categorised none+mild* *Mod+severe* *Comparison with baseline*		No change Base None/Mild to Mod/Severe Base Mod/Severe to None/Mild	36(90.0) 1(2.5) 3(7.5)	36(90.0) 0(0.0) 3(7.7)	32(85.6) 2(5.4) 3(8.1)
Anxiety/nervousness *Comparison with baseline*			McNemars χ^2 result P=0.317	McNemars χ^2 result P=0.248	McNemars χ^2 result P=0.655
Anxiety/nervousness (binary)	None Mild-Severe	27(65.9) 14(34.2)	28(70.0) 12(30.0)	23(59.0) 16(41.0)	22(59.5) 15(40.5)

CNS side effects		Baseline	Week 4	Week 12	Week 24
0=none 1=mild 2=moderate 3=severe	Attended DNA Drop out	41 0 0	40 0 1	39 0 2	37 2 2
Anxiety/nervousness ss *Categorised none* *Mild+Mod+severe* *Comparison with baseline*		No change Base None to Mild/Mod/Severe Base Mild/Mod/Severe to None	36(90.0) 1(2.5) 3(7.5)	27(69.2) 7(17.9) 5(12.8)	24(64.9) 7(18.9) 6(16.2)
Anxiety/nervousness (binary) *Comparison with baseline*			McNemars χ^2 result P=0.317	McNemars χ^2 result P=0.564	McNemars χ^2 result P=0.782
Confusion	None Mild Moderate Severe	38(98.7) 2(4.9) 1(2.4) 0(0.0)	33(82.5) 6(15.0) 1(2.5) 0(0.0)	36(92.3) 3(7.7) 0(0.0) 0(0.0)	32(86.5) 5(13.5) 0(0.0) 0(0.0)
Confusion *Categorised* *none+mild* *Mod+severe* *Comparison with baseline*		No change Base None/Mild to Mod/Severe Base Mod/Severe to None/Mild	38(95.0) 1(2.5) 1(2.5)	38(97.4) 0(0.0) 1(2.6)	36(97.3) 0(0.0) 1(2.7)
Confusion *Comparison with baseline*			McNemars χ^2 result P=0.999	McNemars χ^2 result P=0.317	McNemars χ^2 result P=0.316
Confusion (binary)	None Mild-Severe	38(92.7) 3(7.3)	33(82.5) 7(17.5)	36(92.3) 3(7.7)	32(86.5) 5(13.5)
Confusion *Categorised none* *Mild+Mod+severe* *Comparison with baseline*		No change Base None to Mild/Mod/Severe Base Mild/Mod/Severe to None	30(75.0) 7(17.5) 3(7.5)	33(84.6) 3(7.7) 3(7.7)	29(78.4) 5(13.5) 3(8.1)
Confusion (binary) *Comparison with baseline*			McNemars χ^2 result P=0.206	McNemars χ^2 result P=0.999	McNemars χ^2 result P=0.480
Impaired concentration/attention	None Mild Moderate	27(65.9) 11(26.8) 3(7.3)	25(62.5) 14(35.0) 0(0.0)	28(71.8) 10(25.6) 1(2.6)	26(70.3) 10(27.0) 1(2.7)

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CNS side effects		Baseline	Week 4	Week 12	Week 24
0=none *1=mild* *2=moderate* *3=severe*	Attended DNA Drop out	41 0 0	40 0 1	39 0 2	37 2 2
	Severe	0(0.0)	1(2.5)	0(0.0)	0(0.0)
Impaired concentration/attention *Categorised none+mild Mod+severe Comparison with baseline*		No change Base None/Mild to Mod/Severe Base Mod/Severe to None/Mild	36(90.0) 1(2.5) 3(7.5)	35(89.7) 1(2.6) 3(7.7)	33(89.2) 1(2.7) 3(8.1)
Impaired concentration/attention *Comparison with baseline*			McNemars χ^2 result P=0.317	McNemars χ^2 result P=0.317	McNemars χ^2 result P=0.311
Impaired concentration/attention (binary)	None Mild-Severe	27(65.9) 14(34.2)	25(62.5) 15(37.5)	28(71.8) 11(28.2)	26(70.3) 11(29.7)
Impaired concentration/attention *Categorised none Mild+Mod+severe Comparison with baseline*		No change Base None to Mild/Mod/Severe Base Mild/Mod/Severe to None	30(75.0) 6(15.0) 4(10.0)	29(74.4) 4(10.3) 6(15.4)	29(78.4) 3(8.1) 5(13.5)
Impaired concentration/attention (binary) *Comparison with baseline*			McNemars χ^2 result P=0.527	McNemars χ^2 result P=0.527	McNemars χ^2 result P=0.480
Headache	None Mild Moderate Severe	29(70.7) 9(22.0) 3(7.3) 0(0.0)	33(82.5) 6(15.0) 0(0.0) 1(2.5)	32(82.1) 6(15.4) 1(2.6) 0(0.0)	30(81.1) 6(16.2) 1(2.7) 0(0.0)
Headache *Categorised none+mild*		No change Base None/Mild to Mod/Severe	36(90.0) 1(2.5)	35(89.7) 1(2.6)	35(94.6) 0(0.0)

Final locked data

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CNS side effects		Baseline	Week 4	Week 12	Week 24
0=none 1=mild 2=moderate 3=severe	Attended DNA Drop out	41 0 0	40 0 1	39 0 2	37 2 2
Mod+severe Comparison with baseline		Base Mod/Severe to None/Mild	3(7.5)	3(7.7)	2(5.4)
Headache Comparison with baseline			McNemars χ^2 result P=0.317	McNemars χ^2 result P=0.317	McNemars χ^2 result P=0.157
Headache (binary)	None Mild-Severe	29(70.7) 12(29.3)	33(82.5) 7(17.5)	32(82.1) 7(18.0)	30(81.1) 7(18.9)
Headache Categorised none Mild+Mod+severe Comparison with baseline		No change Base None to Mild/Mod/Severe Base Mild/Mod/Severe to None	36(90.0) 0(0.0) 4(10.0)	31(79.5) 2(5.1) 6(15.4)	27(73.0) 3(8.1) 7(18.9)
Headache (binary) Comparison with baseline			McNemars χ^2 result P=0.046	McNemars χ^2 result P=0.157	McNemars χ^2 result P=0.206
Somnolence/daytime sleepiness	None Mild Moderate Severe	32(78.1) 7(17.1) 2(4.9) 0(0.0)	24(60.0) 11(27.5) 4(10.0) 1(2.5)	23(59.0) 14(35.9) 2(5.1) 0(0.0)	27(73.0) 7(18.9) 3(8.1) 0(0.0)
Somnolence/daytime sleepiness Categorised none+mild Mod+severe Comparison with baseline		No change Base None/Mild to Mod/Severe Base Mod/Severe to None/Mild	37(92.5) 3(7.5) 0(0.0)	39(100.0) 0(0.0) 0(0.0)	34(91.9) 2(5.4) 1(2.7)
Somnolence/daytime sleepiness Comparison with baseline			McNemars χ^2 result P=0.083	McNemars χ^2 result P=0.999	McNemars χ^2 result P=0.564
Somnolence/daytime sleepiness (binary)	None Mild-Severe	32(78.1) 9(22.0)	24(60.0) 16(40.0)	23(59.0) 16(41.0)	27(73.0) 10(27.0)
Somnolence/daytime sleepiness Categorised none		No change Base None to Mild/Mod/Severe	31(77.5) 8(20.0)	30(76.9) 8(20.5)	30(81.1) 4(10.8)

CNS side effects		Baseline	Week 4	Week 12	Week 24
0=none 1=mild 2=moderate 3=severe	Attended DNA Drop out	41 0 0	40 0 1	39 0 2	37 2 2
Mild+Mod+severe Comparison with baseline		Base Mild/Mod/Severe to None	1(2.5)	1(2.6)	3(8.1)
Somnolence/daytime sleepiness (binary) *Comparison with baseline*			McNemars χ^2 result P=0.020	McNemars χ^2 result P=0.020	McNemars χ^2 result P=0.706
Aggressive mood/behaviour	None Mild Moderate Severe	32(78.1) 7(17.1) 2(4.9) 0(0.0)	33(82.5) 7(17.5) 0(0.0) 0(0.0)	34(87.2) 4(10.3) 1(2.6) 0(0.0)	30(81.1) 7(18.9) 0(0.0) 0(0.0)
Aggressive mood/behaviour *Categorised none+mild Mod+severe Comparison with baseline*		No change Base None/Mild to Mod/Severe Base Mod/Severe to None/Mild	39(97.5) 0(0.0) 1(2.5)	37(94.9) 1(2.6) 1(2.6)	36(97.3) 0(0.0) 1(2.7)
Aggressive mood/behaviour *Comparison with baseline*			McNemars χ^2 result Small numbers	McNemars χ^2 result P=0.999	McNemars χ^2 result Small numbers
Aggressive mood/behaviour (binary)	None Mild-Severe	32(78.1) 9(22.0)	33(82.5) 7(17.5)	34(87.2) 5(12.8)	30(81.1) 7(18.9)
Aggressive mood/behaviour *Categorised none Mild+Mod+severe Comparison with baseline*		No change Base None to Mild/Mod/Severe Base Mild/Mod/Severe to None	35(87.5) 2(5.0) 3(7.5)	36(92.3) 0(0.0) 3(7.7)	34(91.9) 1(2.7) 2(5.4)
Aggressive mood/behaviour (binary) *Comparison with baseline*			McNemars χ^2 result P=0.655	McNemars χ^2 result P=0.083	McNemars χ^2 result P=0.564

CNS side effects		**Baseline**	**Week 4**	**Week 12**	**Week 24**
0=none *1=mild* *2=moderate* *3=severe*	Attended DNA Drop out	41 0 0	40 0 1	39 0 2	37 2 2
Abnormal dreams	None Mild Moderate Severe	19(46.3) 13(31.7) 7(17.1) 2(4.9)	28(70.0) 11(27.5) 1(2.5) 0(0.0)	29(74.4) 9(23.1) 0(0.0) 1(2.6)	29(78.4) 6(16.2) 1(2.7) 1(2.7)
Abnormal dreams *Categorised none+mild* *Mod+severe* *Comparison with baseline*	No change Base None/Mild to Mod/Severe Base Mod/Severe to None/Mild		33(85.2) 0(0.0) 7(7.5)	32(82.1) 0(0.0) 7(17.9)	31(83.8) 0(0.0) 6(16.2)
Abnormal dreams *Comparison with baseline*			McNemars χ^2 result P=0.008	McNemars χ^2 result P=0.008	McNemars χ^2 result P=0.014
Abnormal dreams (binary)	None Mild-Severe	19(46.3) 22(53.7)	28(70.0) 12(30.0)	29(74.4) 10(25.6)	29(78.4) 8(21.6)
Abnormal dreams *Categorised none* *Mild+Mod+severe* *Comparison with baseline*	No change Base None to Mild/Mod/Severe Base Mild/Mod/Severe to None		31(77.5) 0(0.0) 9(22.5)	26(66.7) 1(2.6) 12(30.8)	25(67.6) 0(0.0) 12(32.4)
Abnormal dreams (binary) *Comparison with baseline*			McNemars χ^2 result P=0.003	McNemars χ^2 result P=0.002	McNemars χ^2 result P<0.001