

SSAT 066: Statistical Analyses Results

Version 6.0: 22nd January 2018

Primary endpoint

The change in retinol-binding protein/creatinine ratio (PCR) with each regimen over time (measured via nephelometric assay run on Siemens BNII nephelometer).

| | Total=60 | | | | | |
|--|--|---|--|---|-----------------------------------|---|
| | Median (IQR) | | | | | |
| | Baseline | Week 4 | Week 12 | Week 24 | Week 36 | Week 48 |
| | Arm 1: Truvada® (200mg/245mg film coated tablets) one tablet once daily + Raltegravir 400mg (one tablet) twice daily N=20 | | | | | |
| Retinol-binding protein/creatinine ratio (PCR) µg/mmol | 7(6 to 10) Range: 4 to 13 | N=19 6(5 to 8) Range: 4 to 17 | N=19 8(6 to 10) Range: 4 to 23 | N=18 10(9 to 12) Range: 4 to 27 | - | N=17 9(6 to 15) Range: 6 to 29 |
| Change in Retinol-binding protein/creatinine ratio (PCR) µg/mmol wk-ba | | N=19 0(-1 to 2) Range: -8 to 7 p=0.773 | N=19 1(-1 to 4) Range: -7 to 18 p=0.109 | N=17 3(1 to 6) Range: -1 to 23 P<0.001 | - | N=17 2(1 to 6) Range: -6 to 16 P=0.007 |
| | Arm 2: Truvada® (200mg/245mg film coated tablets) one tablet once daily + Dolutegravir 50mg once daily N=20 | | | | | |
| Retinol-binding protein/creatinine ratio (PCR) | N=19 7(6 to 11) Range: 4 to 13 | N=19 8(6 to 13) Range: 5 to 28 | N=19 9(7 to 14) Range: 5 to 20 | N=19 9(6 to 13) Range: 4 to 59 | N=2 6(2 to 9) Range: 2 to 9 | N=18 12(8 to 17) Range: 5 to 92 |

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|--|--|---|--|--|--------------------------------------|---|
| µg/mmol | | | | | | |
| Change in Retinol-binding protein/creatinine ratio (PCR) µg/mmol wk-ba | | N=18 1(-1 to 5) Range: -4 to 16 p=0.109 | N=18 1.5(-1 to 4) Range: -4 to 10 p=0.024 | N=19 1(-2 to 8) Range: -4 to 48 p=0.169 | Small numbers - | N=17 3(0 to 7) Range: -2 to 81 P=0.006 |
| | Arm 3: Stribild®150mg/150mg/200mg/245mg tablet once daily N=20 | | | | | |
| Retinol-binding protein/creatinine ratio (PCR) µg/mmol | N=19 7(5 to 11) Range: 3 to 26 | N=18 9(6 to 13) Range: 1 to 35 | N=19 10(6 to 19) Range: 4 to 32 | N=17 11(8 to 12) Range: 5 to 53 | N=2 12(8 to 15) Range: 8 to 15 | N=19 12(6 to 22) Range: 3 to 71 |
| Change in Retinol-binding protein/creatinine ratio (PCR) µg/mmol wk-ba | | N=18 1(-2 to 3) Range: -12 to 20 p=0.324 | N=19 1(-1 to 6) Range: -7 to 19 p=0.022 | N=16 4(1.5 to 8) Range: 0 to 38 P<0.001 | Small numbers - | N=18 2(0 to 9) Range: -2 to 56 P=0.004 |

p-value using Wilcoxon signed rank test

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Chart showing change in retinol-binding protein/creatinine ratio (PCR) from baseline with each regimen over time (measured via nephelometric assay run on Siemens BNII nephelometer)

