Baseline evaluation in CSF and neuropsychological testing in patients starting Monotherapy

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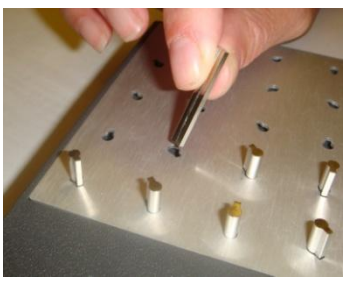
Introduction:

- Previous Monotherapy studies with protease inhibitors (PI) have shown to successfully suppress plasma viral load for up to 54 month
- Concerns remain regarding long- term effects, especially with respect to viral suppression in central nervous system (CNS)
- No prognostic markers for Monotherapy failure do exists for patients considering Monotherapy
- Patients on continous HAART (cont- HAART) and LPV/r Monotherapy (LPV/r Mono) were compaired with a special emphasis on failure rates in CNS and genital compartment

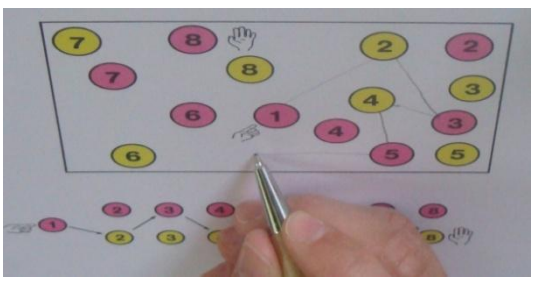
Methods:

- At baseline cerebral fluid (CSF) and neurological (NP) test battery (Fig) was performed in all patients
- In Color Trail 1, the participant is instructed to draw a line between the numbered circles one after the other, following the number sequence
- In Color Trail 2, participant must maintain the sequence of numbers and alternate between pink and yellow
- In EWIA Digit Symbol test participants need to assign correct symbols (90 seconds time) to a digit
- In the Grooved Pegboard ripped sticks have to be placed in grooved holes

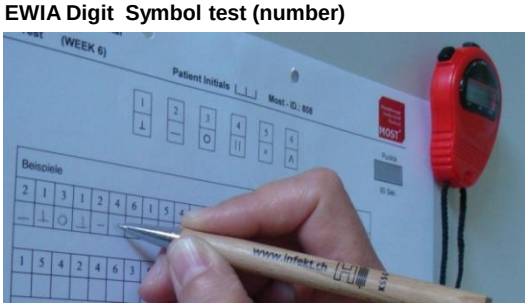
Grooved Pegboard



Color Trail 1 and 2



EWIA Digit Symbol test (number)



Results:

At baseline, all 55 patients (80% men) had undetectable plasma viral load and a CD4 count of 502 ±214 cl/ml (CD4% 29.1 ±9.1). Mean CD4 nadir was 167 ±120 (CD4% 14 ±9.0). Only one patient had a CSF viral load of 82 cp/ml (kept on cont-HAART). Mean therapy duration in these patients was 5.8 years (1.9-13.6 years). The average age was 45.3 ±9.6 years. Treatment groups didn`t differ at baseline, and no significant correlation was found between NP variables and patient characteristics (age, CD4, CD4 nadir). Test results were compared with historical controls (see table and references).

Tab. 1: Neuropsychological Information at baseline (mean / ± SE) compared with historical controls (1-2)

	This study	Historical controls		
	(baseline)	HIV+ not treated	HIV+ treated	HIV negative
Color trail 1 (sec)	54 (±26.2)	50.4 (±25.6)	49.8 (±19.9)	74.1 (±22.2)
Color trail 2 (sec)	103 (±46.0)	113.8 (±98.8)	106.5 (±31.8)	124.5 (±37.2)
EWIA Digit (number)	52 (±15.7)	n.d.	n.d.	n.d.
Grooved pegboard (dominant, sec)	76 (±18.9)	92.8 (±31.4)	87.0 (±36.5)	86.5 (±21.3)
Grooved pegboard (non.dom, sec)	84 (±19.6)	n.d.	n.d.	102.7 (±25.2)

References and Acknowledgment:

1. Neurocognitive performance enhanced by highly active Antiretroviral therapy in HIV- infected women AIDS 2001, 15: 341-345
2. The International Dementia Scale: A new rapid screening test for HIV dementia AIDS 2005, 19: 1367-1374

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Conclusion:

- With the exception of one patient, viral load in CSF was suppressed and patients showed normal NP-test results compaired to other HIV cohorts