Supplemental Information on methods and Figures 2 & 3

Detailed information on Methods and Results

Further Exclusion Criteria and Randomization process

Further exclusion criteria were pregnancy, active AIDS defining disease necessitating antibiotics or chemotherapy at the time of screening and presence of serum hepatitis B surface antigen or a history of treatment limiting side effects caused by LPV/r. The study included highly motivated patients able to understand the investigational nature of this study and willing to participate in additional procedures, such as lumbar puncture. The study was approved by all local ethical review boards and all patients signed a written informed consent.

Randomization was stratified by gender, center and current type of treatment (PI or NNRTI) with a minimization procedure to balance stratified randomization.

Neuropsychological tests

At baseline, week 48 and study termination, a neuropsychological test battery was performed by trained study nurses, or physicians. We performed the Color Trail 1 and 2 test, EWIA DIGIT Symbol test, and Grooved pegboard test (with dominant and non-dominant hand). This test battery was chosen in collaboration with Victor Valcour at the University of Hawaii. A detailed analysis will be presented elsewhere.

The Color Trail Test is a test of visual attention, graphomotor sequencing and executive processing abilities. In Color Trail 1, the patient is instructed to draw a line between the numbered circles one after the other, following the number sequence.

Color trial 2; the patient must maintain the sequence of numbers and alternate between pink and yellow.

In the EWIA Digit Symbol Test the patient needs to assign correct symbols to a digit within a time limit of 90 seconds. The test explores concentration and speed of mental processing.

To explore fine motor functioning the Grooved Pegboard Test was performed. Ribbed sticks have to be placed in grooved holes with the dominant respectively the non-dominant hand.

Premature study termination

On September 24, 2008 the protocol committee decided to stop the trial after virological failure was observed in six patients exclusively under MT. At that time, 29 and 31 patients had been randomized to the MT and CT arm, respectively. An additional 13 patients with previous CT had already reached 48 weeks and had switched to MT. These patients are referred to as delayed switch group (DS). All patients under CT maintained full virologic suppression.

Additional results

HIV-RNA in genital compartment

30 male and 17 female patients provided a genital secretion sample at baseline. HIV-RNA in seminal plasma was detectable in 6 patients at baseline (range 2.0-3.2 $\log_{10}$ cp/ml). At the termination visit, 1 in 16 MT-patients vs. 0 in 15 CT patients had detectable HIV-RNA in semen (2.2 $\log_{10}$ cp/ml). A total number of 22 CVS-samples were available from patients on CT and 18 on MT. Only one woman had HIV-RNA detectable in CSV in two samples on CT, while her third sample after delayed switch to MT had an undetectable HIV-RNA.

Neuropsychological performance

Overall, results of neuropsychological (NP) tests demonstrated a slight improvement from baseline to the termination visit but the changes were independent of the treatment assignment and the differences were not considered to be of clinical relevance. In addition, the changes in NP test results did not differ between patients who had detectable HIV-RNA in CSF vs. those with suppressed RNA in CSF.

Figure 2: Flowchart of Study design

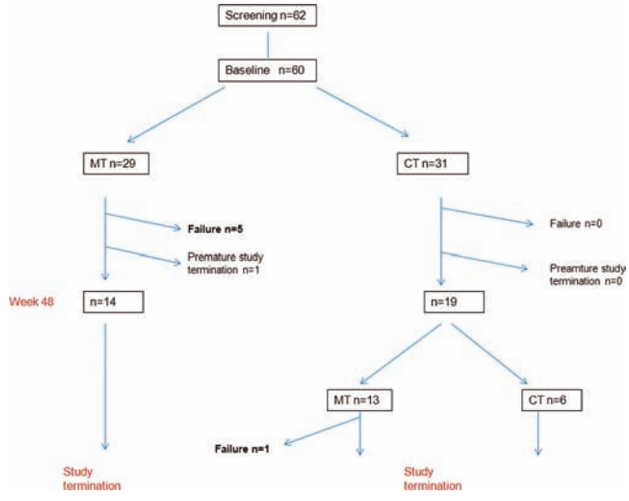

Figure 3: Low level viremia during MT and CT (13 patients in the CT group switched to MT at week 48), the six failing patients are excluded