Efficacy of a Maintenance Four-Days-A-Week Regimen, the ANRS1624D trial

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Abstract

Purpose: a 4 days a week ARV (D4W) regimen in HIV+ patients with controlled VL and a good adherence to ART, in order to evaluate its efficacy in controlling virological and immunological parameters, and the impact of adherence to the study strategy or adherence to the D4W therapy in terms of virological and immunological parameters.

Background

Given the high recommended duration of ART and the need for long-term therapy, strategies reducing ART intake would be of interest to improve patients adherence. The efficacy of a short-cycle therapy strategy with planned short breaks from ARV could be an alternative to reducing long-term therapy effects and costs.

Primary end point: Assesment of therapeutic efficacy, as defined by a cumulative plasma viral load (cVL) <50 copies/ml, within four weeks during the 48 weeks of follow-up (virological success).

Secondary end points: virological suppression, drug treatment, changes in CD4, CDC classification, metabolic parameters, safety parameters and tolerability.

Methods

A total of 110 participants (100 included) were included in the study (42 women and 58 men). Using the last week recall at each visit, the adherence rate was calculated for each participant.

Results

Changes from baseline in biological parameters at week 48

<table>
<thead>
<tr>
<th>Biological parameter (Baseline)</th>
<th>N=100</th>
<th>Mean (SD)</th>
<th>ANOVA (F-value)</th>
<th>P-value</th>
<th>Mean (SD)</th>
<th>ANOVA (F-value)</th>
<th>P-value</th>
<th>Mean (SD)</th>
<th>ANOVA (F-value)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>401</td>
<td>13.4 (0.7)</td>
<td>4.0 (0.7)</td>
<td>0.91</td>
<td>13.4 (0.7)</td>
<td>4.0 (0.7)</td>
<td>0.91</td>
<td>13.4 (0.7)</td>
<td>4.0 (0.7)</td>
<td>0.91</td>
</tr>
<tr>
<td>CD4 cell count</td>
<td>532</td>
<td>588 (29)</td>
<td>588 (29)</td>
<td>0.00</td>
<td>588 (29)</td>
<td>588 (29)</td>
<td>0.00</td>
<td>588 (29)</td>
<td>588 (29)</td>
<td>0.00</td>
</tr>
<tr>
<td>CD8 cell count</td>
<td>859</td>
<td>521 (28)</td>
<td>521 (28)</td>
<td>0.00</td>
<td>521 (28)</td>
<td>521 (28)</td>
<td>0.00</td>
<td>521 (28)</td>
<td>521 (28)</td>
<td>0.00</td>
</tr>
<tr>
<td>log10 cVL</td>
<td>4.61</td>
<td>4.44 (0.3)</td>
<td>4.44 (0.3)</td>
<td>0.66</td>
<td>4.44 (0.3)</td>
<td>4.44 (0.3)</td>
<td>0.66</td>
<td>4.44 (0.3)</td>
<td>4.44 (0.3)</td>
<td>0.66</td>
</tr>
<tr>
<td>log10 7-HCU</td>
<td>1.35</td>
<td>1.35 (0.4)</td>
<td>1.35 (0.4)</td>
<td>0.74</td>
<td>1.35 (0.4)</td>
<td>1.35 (0.4)</td>
<td>0.74</td>
<td>1.35 (0.4)</td>
<td>1.35 (0.4)</td>
<td>0.74</td>
</tr>
<tr>
<td>log10 Plasma creatinine</td>
<td>1.35</td>
<td>1.35 (0.4)</td>
<td>1.35 (0.4)</td>
<td>0.74</td>
<td>1.35 (0.4)</td>
<td>1.35 (0.4)</td>
<td>0.74</td>
<td>1.35 (0.4)</td>
<td>1.35 (0.4)</td>
<td>0.74</td>
</tr>
</tbody>
</table>

Conclusion

Over 48 weeks, maintenance ARV therapy with 4 days a week regimen was effective in these patients with suppressed VL under 2 nucleosides and either a P/ or a NRTI, resulting in a success rate of 96%. High adherence to therapy was assessed by questionnaires and MEMS caps. A comparative randomized trial and longer follow-up will further inform the efficacy and sustainability of this strategy.

Acknowledgements

References

1. European AIDS Clinical Society (EACS) and European Centre for Disease Prevention and Control (ECDC). European guidelines on the management of HIV-1 infections in adults and adolescents. 2014. 2. Smith CA, Bäckström M, Berson 

Poster

Monitoring Therapeutic Success of Maintenance 4-Days-A-Week Regimen in HIV+ Patients with Controlled VL


Abstract

Methods

Adherence to the study strategy

Adherence to the study strategy and event Monitoring System (NSEM) were investigated using self-reported questionnaires and MEMS caps. Percentages of patients with self-reported adherence rates of >100% and <100% at each participation in the study was investigated. Overall, the percentage of participants with a cumulative adherence rate of ≥95% was 65% for D4W therapy and 70% for the baseline study, respectively.