Results

Figure 1: Patient Flowchart

Figure 2: Change in HIV DNA (log10 copies/10^6 PBMCs)

Figure 3: Change in CD4 count (cell/mm3)

Figure 4: HIV specific T-cell responses

Table 1: Baseline Characteristics

Table 2: Safety — Serious Adverse Events

Table 3: Median (IQR) Change in HIV DNA (Baseline to Week 56) in Blood Compartment and Reticular Tissue

Table 4: Mean (SD) Changes in CD4/CD8 Count (Baseline to Week 56)

Background

Elimination of HIV-1 infection cannot be achieved by current potent highly active antiretroviral therapy (HAART) regimens. The identification of latently infected cells represents a major challenge in the eradication of HIV infection. The development of an effective vaccine was greatly hindered by the persistent presence of virus in uninfected cells. Our approach was to intensify antiretroviral treatment in latently infected patients with a re-introduction of a novel HIV-1 vaccine in order to increase viral set piece numbers and allow immune surveillance

The ErlBA02 trial was a multicenter, randomized, non-comparative controlled study of ART intensification plus dual raltegravir-maraviroc (RAL/MVC) booster vaccine in HIV-1 infected patients with long-term viral suppression.

Study design

Aiming at a margin of biological importance (RAL/MVC doubling in 8 weeks, subjects were randomized 1:1): A: RAL/MVC Continue intensification alone for 48 weeks; B: RAL/MVC + DNA prime/rAd5 boost: Continue intensification for 48 weeks. Subjects were randomized (1:1) to: A: RAL/MVC Continue intensification alone for 48 weeks; B: RAL/MVC + DNA prime/rAd5 boost: Continue intensification for 48 weeks. Subjects were randomized (1:1) to:

Eligibility criteria

- adults (18-70 years) with HIV-1 infection
- ≤2 years of antiretroviral therapy (ART) ≤18 years of age
- ≤15 years of age
- ≥18 years of age
- ≤15 years of age
- ≥18 years of age
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- ≥18 years of age
- ≤15 years of age

Methods

In this phase IIb trial, ART naïve adults in two intervention arms. In one arm, participants were randomized to take the RAL/MVC intensification regimen alone for 48 weeks. The other arm received the addition of a novel HIV-1 vaccine. In one arm, participants were randomized to take the RAL/MVC intensification regimen alone for 48 weeks. The other arm received the addition of a novel HIV-1 vaccine. In one arm, participants were randomized to take the RAL/MVC intensification regimen alone for 48 weeks. The other arm received the addition of a novel HIV-1 vaccine. In one arm, participants were randomized to take the RAL/MVC intensification regimen alone for 48 weeks. The other arm received the addition of a novel HIV-1 vaccine.

Conclusions

- RAL/MVC intensification with or without HIV-rAd5 vaccination did not significantly reduce the total HIV-DNA reservoir in either peripheral blood or reticular tissue.
- RAL/MVC intensity alone decreased the HIV-1 reservoir by over 0.5 log DNA copies/PBMCs in one patient.
- There was no significant effect of RAL/MVC intensification with or without HIV-rAd5 vaccination on CD4 or CD8 cell counts.
- DNA prime with HIV-rAd5 boost vaccination was safe and induced significant T-cell responses against Gap, Pol, Env in HIV-infected patients on long-term suppressive ART.

The ErlBA02 Study Group

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