METHODS:

Prospective, monocentric, observational study analysing all subjects diagnosed with PHI from July 2013 to April 2018 at INMI L. Spallanzani.

Diagnosis of PHI was made if at least one of the following criteria was met: 1) positive HIV viral load (2,000 copies/mL) and negative very early Ab/Ac Combo or Western Blot (WB) test; 2) positive HIV Ab/Ac Combo test and negative or undetermined WB test; 3) positive HIV Ab/Ac Combo test and incomplete WB test (negative p24 protein reaction); 4) recent infection confirmed by a positive PHI-1 EIA or WB test and a documented negative PHI-1 EIA within the previous 6 months.

CDART was initiated as soon as possible after HIV diagnosis, before availability of ART, with one of the following options:

- 3-drug group: RAL 400 mg b.i.d. + DRV/r 800/100 mg or RAL/r 600/150 mg q.d. + TDF/FTC 245/200 mg q.d.
- 3-drug group: DTG 50 mg q.d. + TDF/FTC 245/200 mg q.d. (from May 2015)

Statistical analysis

Follow-up accrued from the start of CDART (baseline, 0) until either virological or immunological outcome achievement or last observation, for a maximum observation time of 72 weeks.

RESULTS:

Virological and immunological outcomes at any time point were similar between the two treatment groups [Table 4-6].

In PHI, an intensified 4-drug regimen including RAL and DRV/r and a 3-drug DTG-based CDART did show a comparable virological response.

Both strategies were associated with a highly effective virological suppression, proving to be both valid and comparable treatment options for this stage of infection. The trend towards a better virological performance of 3-drug regimen, especially in patients with lower baseline virology, was no longer confirmed after adjustment by adherence level as time-dependent co-variates, supporting the role of adherence as possible limiting factor of 4-drug high-pill regimen.