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SISTEMA SANITARIO REGIONALE IRCCS LAZZARO SPALLANZANI

An early proactive switch to elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) is effective in maintaining virologic control and improving quality of life (QoL) in patients with a primary HIV-1 infection (PHI): an interim analysis of a phase IV clinical trial (ESTER study)

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BACKGROUND

Although switching from a PI/b or NNRTI-based therapy to an INSTI regimen is a recognized strategy in CHI, it has not been tested in PHI [1].

REFERENCE: 1. Hodder S, JAIDS 2018.

The aim of our study was to evaluate virological and immunologic efficacy, adherence, and QoL of an early simplification strategy in HIV+ pts starting an intensified ART during PHI.

METHODS

Study design:

- **ESTER** is a prospective, monocentric, pilot 96-week single-arm trial, conducted at INMI L. Spallanzani from March 2017 to December 2018.

Study population:

- We included in the study 30 pts with PHI who started a 4 drug regimen→ **RAL 400 mg b.i.d. + DRV/r 800/100 mg or DRV/c 800/150 mg q.d. + TDF/FTC 245/200 mg q.d.** with a wild type GRT and who achieved the virologic suppression (HIV-RNA < 40 cp/ml).

Study procedures:

- At baseline visit (BL) all pts were switched to **E/C/F/TAF**.
- Virologic failure (VF) was defined as two consecutive HIV-1 RNA tests ≥ 40 copies/ml.
- Viral and immunologic parameters, residual viremia by ultrasensitive (US) assay (HIV-RNA <5cp/ml) and PBMC HIV-DNA were evaluated at BL, w 24 , w 48 and w 96.
- Adherence was measured trough self reported questionnaire including the Visual Analogue Scale (VAS) at BL, w24, w48 and w96.
- QoL was assessed through both VAS and the 30-item version of the Medical Outcome Study-HIV Health Survey (MOS-HIV) score at BL, w24, w48 and w96.

We report preliminary data until the w 48 visit.

RESULTS

Table 1. Patients characteristics (N=30)

	(N=30)
Male gender*	29 (96.7%)
Age**	34 (27-46)
Risk Factor*	
- MSM	26 (86.7%)
- Heterosexual	4 (13.3%)
Non Italian born*	4 (13.3%)
BL CD4 cells count	
- Median CD4 cell count, cell/mm³**	667 (520-773)
- CD4 ≥ 500 cell/mm3*	23 (76.7%)
- CD4 200-499 cell/mm3*	7 (23.3%)
BL CD8 cells count	
Median CD8 cell count, cell/mm³**	616 (531-838)
BL CD4/CD8 > 1 ratio*	14 (46.7%)
BL HIV DNA cp per 10^6 PBMC**	2042 (1228-4000)
Boosted PI in the regimen:	
- TDF/FTC + DRV/c + RAL	22 (73.3%)
- TDF/FTC + DRV/r+RAL	8 (26.7%)
- HIV duration before the switch, month**	6.5 (4.7-8.1)

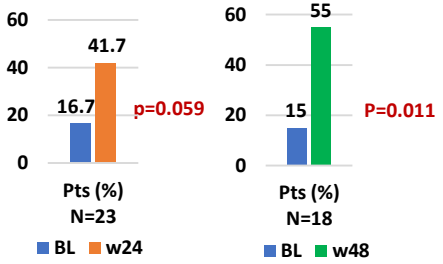
*n (%); ** median (interquartile range)

VIROLOGICAL OUTCOMES

- VF* occurred in 2 patients (6.6%).
- 1 VF occurred at w 48, 1 VF occurred at BL.
- The patient failed at w 48 presented colitis for 10 days, 20 days before the VF.
- The two patients are still on therapy with E/C/F/TAF, with virological resuppression.
- All viremic patients had HIV-RNA<200 cp/ml.

*VF was defined as HIV-1 RNA test ≥ 40 cp/ml confirmed after 2w

Proportion of pts with US HIV-RNA <5cp/ml:



PBMC Log HIV-DNA cp/ml (mean value):

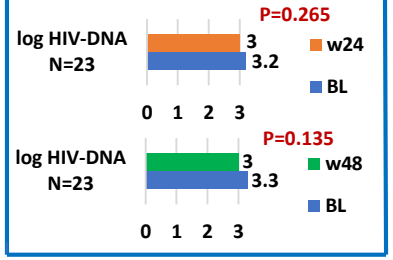


Table 3. QOL survey using 30 item MOS-HIV* and VAS scale

N=23	BL mean (SD)	W24 mean (SD)	p-value
Physical functioning	**94.6 (12.2)**	**97.5 (7.3)**	**0.046**
Pain	**84.1 (21.9)**	**93.7 (12.0)**	**0.049**
State of health (VAS)	82.5 (20)	88 (15.8)	0.173
N=18	**BL mean (SD)**	**W48 mean (SD)**	**p-value**
Physical functioning	94 (13.6)	94 (12.4)	0.630
Pain	81.5 (23.2)	88.3 (15)	0.320
State of health (VAS)	83.7 (20.5)	87.8 (17.3)	0.283

*Only the significant results are reported.

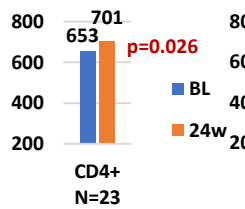
Table 2. Patients-reported adherence at W24 and W48

N=23	w1 before BL	W24	P value
Missed doses*	5 (21.7%)	2 (8.7%)	0.083
>2h delayed doses*	7 (30.4%)	7 (30.4%)	1
>1day treatment interruption*	1 (0.80-1.34)	0 (0%)	0.180
Adherence perception (VAS)**	98.5 (5.5)	98.5 (3.9)	0.718
N=18	**w1 before BL**	**W48**	**P value**
Missed doses*	5 (29.4%)	2 (11.8%)	0.180
>2h delayed doses*	6 (33.3%)	6 (33.3%)	1
>1day treatment interruption*	0 (0%)	0 (0%)	1
Adherence perception**	98.6 (5.9)	98.9 (3.2)	0.968

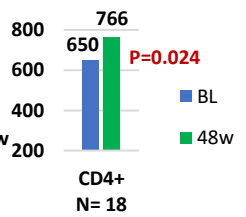
*n (%); ** median (interquartile range)

IMMUNOLOGICAL OUTCOMES

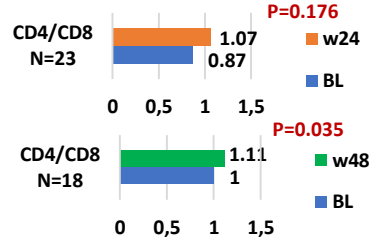
CD4 at BL vs w24 (mean value):



CD4 at BL vs w48 (mean value):



CD4/CD8 at BL vs w24 and BL vs w48 (mean value):



CONCLUSIONS

Starting cART with an intensified quadruple regimen in patients with PHI has been represented a common clinical practice in recent years, even if it is not the standard of care [2]. In those patients, an early switch to E/C/F/TAF was effective in maintaining virologic control, by reducing low level viral replication, and in improving immunological recovery.

REFERENCE: 2. Freng Q, BMJ 2019