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Tolerability and compliance of tenofovir/emtricitabine/rilpivirine (TDF/FTC/RPV) in HIV post exposure prophylaxis

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Background

Post-exposure prophylaxis (PEP) has been used to decrease risk of HIV transmission after risk exposure and regimen completion is worldwide recommended for 28 days. The choice of antiretroviral regimen should maximize uptake and completion rates.
Since October 2016, French guidelines recommended tenofovirDF/emtricitabine/rilpivirine (TDF/FTC/RPV) as first choice of PEP. Limited data are available on tenofovirDF/emtricitabine/rilpivirine tolerability in PEP.
We present the final results of a study that evaluate TDF/FTC/RPV in PEP.

Inclusion/Non-inclusion

Inclusion criteria
- Subject seeking care in one of the 4 French centers of « Pays de la Loire » area (CHU Nantes, CHD La Roche sur Yon, CH Le Mans, CH Saint Nazaire) after a sexual or non-sexual HIV exposure
- Adult over 18 years old
- Oral informed consent
- Indication of PEP according to the French guidelines (Oct 2016 version)
- HIV-uninfected subjects

Non-inclusion criteria
- Subject not willing or refusing to participate
- Any medication contraindicated with TDF/FTC/RPV

Objectives

To evaluate safety, tolerability, adherence and efficacy of a 28-day course of TDF/FTC/RPV (1 pill/day with food) started within 48-hours of at risk exposure to HIV.

Methods

Prospective, observational, open-label, multicenter study conducted in 4 centers of « Pays de la Loire » area, France, from 21st March 2016 to 21st March 2017.
- At baseline, patients were prescribed TDF/FTC/RPV, 1 tablet, once daily with food for 28 days
- Subjects had to start TDF/FTC/RPV less than 48 hours after HIV exposure
- Inclusion and baseline visit had to be done less than 4 days after starting PEP if they started PEP in the emergency unit
- Socio-demographic characteristics, HIV risk behavior (if non occupational exposure) and context of the risk event were collected
- At W4, all participants were contacted by phone to collect adherence, side effects and completion of the regimen
- At baseline, patients were proposed a blood test including HIV, HBV, HCV serology, TPHA VDRL, ALT/AST, hemogram, serum creatinine
- Blood samples for biological and/or serological data were prescribed at, W2, W4, W8 and W16

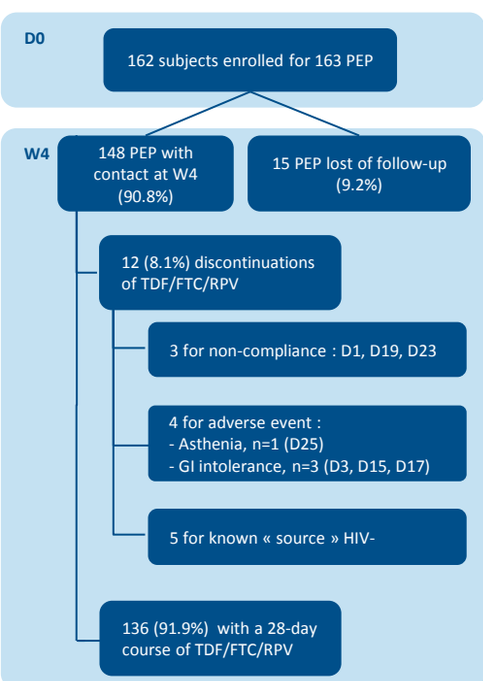
Results

• Baseline characteristics of the 162 subjects (163 PEP) enrolled between March 2016 and March 2017

n (%)	Total n=162	Non sexual risk 13 (8%) (occupational n=8 non occupational n=5)	Sexual risk 149 (92%)	Type of sexual exposure	
				Heterosexual 65 (43.6%)	MSM 84 (56.4%)
Male	120 (74.1)	4 (30.8)	116 (77.9)	32 (49.2)	84 (100)
Age, years, median (IQR)	29 (25-40)	36 (26-44)	29 (25-39)	29 (25-37)	29.5 (25-41)
Born in France	137 (84.6)	11 (84.6)	126 (84.6)	49 (75.4)	77 (91.7)
High level education	84/129 (65.1)	7/10 (70)	77/119 (64.7)	32/52 (61.5)	45/67 (67.1)
Currently working	84/133 (63.2)	9/13 (69.2)	75/120 (62.5)	32/52 (61.5)	43/68 (63.2)

• Baseline characteristics of the 163 PEP (162 subjects)

n (%)	Total n=163	Non sexual risk 13 (8%) (occupational n=8 non occupational n=5)	Sexual risk 150 (92%)	Type of sexual exposure	
				Heterosexual 65 (43.3%)	MSM 85 (56.7%)
Use of condom	68 (46)	-	68 (46)	34 (54)	34 (40)
Known « source » HIV+	27 (16.6)	6 (46.2)	21 (14)	3 (4.6)	18 (21.2)
HIV RNA < 50 c/mL	7 (25.9)	0 (0)	7 (33.3)	0 (0)	7 (38.9)
HIV RNA ≥ 50 c/mL	3 (11.1)	2 (33.3)	1 (4.8)	1 (33.3)	0 (0)
Unknown	17 (63.0)	4 (66.7)	13 (61.9)	2 (66.7)	11 (61.1)
HCV serology negative	140/140 (100)	9/9 (100)	131/131 (100)	57/57 (100)	74/74 (100)
HBV status					
Chronic HBV infection (HBs Ag +)	1/126 (0.8)	0/8 (0)	1/118 (0.8)	1/57 (1.8)	0/61 (0)
Vaccinated (HBs Ab +, HBc Ab -)	71/123 (57.7)	5/8 (62.5)	66/115 (57.4)	31/55 (56.4)	35/60 (58.3)
Past HBV infection (HBs Ab +/-, HBc Ab +)	6/123 (4.9)	0/8 (0)	6/115 (5.2)	3/55 (5.5)	3/60 (5)
No HBV protection (HBs Ab -, HBc Ab -)	44/123 (35.8)	2/8 (25.0)	42/115 (36.5)	21/55 (38.2)	21/60 (35)
History of syphilis (VDRL+)	8/133 (6.0)	0/2 (0)	8/131 (6.1)	1/56 (1.8)	7/75 (9.3)

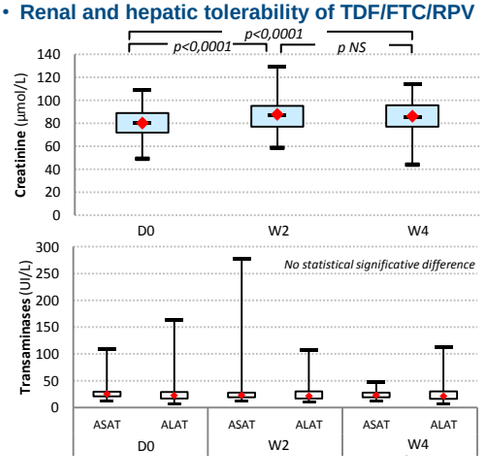


• Tolerability of TDF/FTC/RPV in the 148 subjects with phone contact at W4

	%	Grade 1-2	Grade 3
Subjects with at least one AE	69.6		
Adverse events >5%			
Asthenia	19.5	95.9	4.1
Nausea	12.7	96.9	3.1
Diarrhea	11.2	89.3	10.7
Abdominal pain	8.8	95.5	4.5
Insomnia	5.6	92.9	7.1
Headache	6.0	93.3	6.7
Dizziness	5.6	92.9	7.1

No serious AE (grade 4) occurred.

• Renal and hepatic tolerability of TDF/FTC/RPV



• Results at W16

HIV serology
- Available in 99/163 subjects (60.7%)
- 100% of them are negative

HCV serology
- Available in 55/163 subjects (33.7%)
- 100% of them are negative

HBV serology
- Available in 35/163 subjects (21.5%)
- No change / D0

Syphilis
- No diagnosis of recent infection (n=85)

Conclusion

- This study is the first one to evaluate TDF/FTC/RPV in HIV Post Exposure Prophylaxis in France.
- In this context of anxiety related to the fear of contamination, adverse events were frequent. However only 4 adverse events led to premature discontinuation of PEP.
- 9.2% of subjects were lost of follow up at W4.
- Among subjects with phone contact at W4, completion rate of the 28-days course of TDF/FTC/RPV was high at 91.9%. 12 subjects discontinued (4 for adverse events).
- Our results validate the experts' recommendation of TDF/FTC/RPV in PEP in France.

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