# Compliance and safety of tenofovirDF/emtricitabine/rilpivirine in post-exposure prophylaxis

WEPECO918

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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 interim results of a an ongoing study of PEP with this combination.

## 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 post-exposure prophylaxis according to the French guidelines (Oct 2016 version)
- HIV-uninfected subjects

**Non-inclusion criteria**

- Patient not willing or refusing to participate
- Patient <18 years old
- 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 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
- Patients were proposed a blood test including HIV, HBV, HCV serology, TPHA VDRL, ALT/AST, hemogram , serum creatinine
- 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.
- Blood samples for biological and/or serological data were prescribed at, W2, W4, W8 and W16.

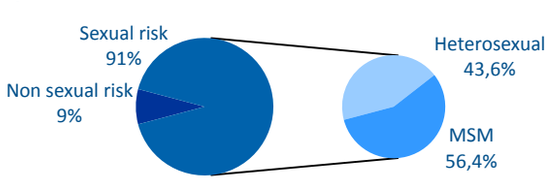
## Results

- **Baseline characteristics of the 129 patients enrolled (130 PEP) from March 21 to dec 31, 2016**

| | Total N=129 | | Non sexual risk N=12 (occupational n=7 Non occupational n=5) | | Sexual risk N=117 | | Type of sexual exposure: Heterosex. N=51 | | Type of sexual exposure: MSM N=66 | |
|---|---|---|---|---|---|---|---|---|---|---|
| Male, n (%) | 97 | (75.2) | 4 | (33.3) | 93 | (79.5) | 27 | (52.9) | 66 | (100) |
| Age, years, median (IQR) | 29 | (25-38) | 32.5 | (26-43) | 29 | (25-38) | 29 | (24-34) | 29 | (26-40) |
| Born in France, n (%) | 107 | (82.9) | 10 | (83.3) | 97 | (82.9) | 38 | (74.5) | 59 | (89.4) |
| High level education, n (%) | 71/100 | (71) | 7/10 | (70) | 64/90 | (71.1) | 27/41 | (65.9) | 37/49 | (75.5) |
| Currently working, n (%) | 67/103 | (65) | 8/12 | (66.7) | 59/91 | (64.8) | 25/41 | (61) | 34/50 | (68) |
| Known « Source » HIV+*, n (%) | 22 | (17) | 5 | (41.7) | 17 | (14.5) | 3 | (5.9) | 14 | (21.2) |
| Condomless exposure, n (%) | _ | | _ | | 59 | (50.9) | 23 | (46) | 36 | (54.6) |
| | | | | | | | | | | |
| TPHA-VDRL negative, n (%) | 91/105 | (86.7) | 2/2 | (100) | 89/103 | (86.4) | 43/45 | (95.6) | 46/58 | (79.3) |
| HBV serology negative** , n (%) | 32/98 | (33.3) | 2/6 | (33.3) | 30/90 | (33.3) | 16/44 | (36.4) | 14/46 | (30.4) |
| HCV serology negative, n (%) | 110/110 | (100) | 7/7 | (100) | 103/103 | (100) | 47/47 | (100) | 56/56 | (100) |

*HIV RNA≥50 c/ml 3/22 (13.6%), viral load<50 c/ml 4/22 (18.1 %), HIV RNA unknown 15/22 (68.2%), ** HBs Ag, neg + HBs Ab neg + HBc Ab neg. C

- **Types of risk exposure**




- **Situation of the subjects at W4**

| | n | % |
|---|---|---|
| Completed the 28-days course of RPV/TDF/FTC | 113 | 87.6 |
| Lost to follow-up ¤ | 12 | 9.7 |
| Prematurely stopped the treatment : | 8 | 6.4 |
| - HIV negative source patient# | 4 | 50 |
| - Patient'decision at D1 (sexual exposure) | 1 | 12.5 |
| - Adverse events leading to discontinuation: | 3 | 37.5 |
| - Asthenia* | 1 | 33.3 |
| - GI disturbances ** | 2 | 66.7 |

¤ sexual n= 8, non sexual n=4, #sexual n= 1, non sexual n=3, * at D25
** at D3: abdominal pain, nausea and vomiting, and at D25: nausea and vomiting

- **Tolerability of TDF/FTC/RPV in the 117 subjects with phone contact at W4**

| | % |
|---|---|
| Subjects with at least one AE | 68.4 |
| Adverse events >5% | |
| Asthenia | 19.5 |
| grade 1-2 | 94.7 |
| grade 3 | 5.2 |
| Nausea | 12.3 |
| grade 1-2 | 100 |
| grade 3 | 0 |
| Diarrhea | 11.8 |
| grade 1-2 | 97 |
| grade 3 | 3 |
| Abdominal pain | 10.8 |
| grade 1-2 | 95.2 |
| grade 3 | 4.8 |
| Insomnia | 6.2 |
| grade 1-2 | 100 |
| grade 3 | 0 |
| Headache | 5.6 |
| grade 1-2 | 100 |
| grade 3 | 0 |
| Dizziness | 5.1 |
| grade 1-2 | 100 |
| grade 3 | 0 |

No serious AE (grade 4) occurred

**Among the 51 participants with an HIV test at W16, none acquired HIV through W16 of follow-up**

## 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 3 adverse events led to premature discontinuation of PEP.
- Completion rate was high with 87.6% of subjects completing the 28-days course of TDF/FTC/RPV.
- Our preliminary results validate the experts' recommendation of TDF/FTC/RPV in PEP in France.

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