Safety and Efficacy of YELLOW FEVER Vaccine in HIV-infected patients (EP46 ANRS NOVAAA Trial)

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YELLOW FEVER VACCINE-ASSOCIATED VISCEROTROPIC DISEASE OR NEUROLOGIC DISEASE (YEL-AVD, YEL-AND) IN HIV-INFECTED PATIENTS

- YF17D vaccine can be responsible for serious adverse events in HIV-patients, even if infrequent: a case of fatal encephalitis in a patient with 108 CD4/mL

- Difficult to assess risk of travelers - retrospective studies:
  - 450 HIV-infected persons who received YF vaccine reported no additional serious adverse events.
  - Limited subset of adults with a CD4 counts <200 per mm3

- No large prospective, randomized trials to address the safety and efficacy of YF vaccine

HIV-INFECTED PATIENTS 2009, SWISS COHORT: PNRT IN 78 RECENTLY VACCINATED

- lower reactive PRNTs
- more often non protective
- a more rapid decline
- serious adverse events up to 3%?

Cellular immunity poorly explored in a routine YF17D vaccine in HIV-infected pts

Neutralization test (PNRT$_{50}$) correlates with protective immunity to YF but is time-consuming

Particular concern in France
- HIV-infected African patients living in France and travelling in endemic YF countries
- Limited availability of PNRT$_{50}$
Objectives

• To compare the virological and immune responses in HIV-positive and HIV-negative individuals YF naive-vaccine populations
• To evaluate safety and tolerance of YFV in HIV-positive populations
• To develop specific tools for the evaluation of YFV humoral and cell-mediated immunity

Clinical trial phase III: Universitary Hospitals in Paris, specialized in travel medicine

• 40 HIV-1-infected patients, under HAART, CD4 T-cell count > 350 for the last 12 months, plasma HIV RNA level <50 cp/mL for at least 6 months
• A least 50% of HIV-pts had a nadir < 200 CD4/μL
• 30 pts VIH- controls, matched on age
ESSAI EP46 ANRS NOVAA: COMPARATIVE FOLLOW-UP IN 40 HIV-INFECTED AND 30 CONTROL PATIENTS

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ESSAI EP46 ANRS NOVAA - CALENDAR

2011 January
- First inclusions
- Development-Validation of a pseudotype-based neutralizing ab assays
- Validation of a NS3 Elispot

2012 January
- End of inclusion in 2012
- Analysis of the samples

2013 January
- Final results