

ANRS 0146s NOVAA TEN - Information for Researchers

Yellow fever vaccination in HIV-1-infected individuals:
Study of long-term immune responses

At a glance	Principal Investigator: Dr. Nathalie COLIN DE VERDIER
	Organization/teams: Center for Methodology and Management: Prof. Laurence MEYER /INSERM SC10-US19 Investigating Centers: • Dr. Nathalie Colin de Verdère, Infectious Diseases Department, Saint Louis Hospital, Paris • Prof. Jade Ghosn, Department of Infectious and Tropical Diseases, Bichat Claude Bernard Hospital, Paris • Prof. Odile Launay, Vaccinology Clinical Research Unit at Cochin Hospital, Paris
	Start Date: June 2025 Study End Date: June 2025 + 6 months after the date of the last visit by the last participant
	Number of participants: 60 participants: 40 people living with HIV and 20 controls
	Study status: Currently recruiting
	Condition: HIV-1
	Sponsored by: Inserm - ANRS MIE
	Funded by: NA
The project	This is a non-randomized, multicenter study comparing two parallel groups initially consisting of 40 HIV-positive subjects and 20 HIV-negative subjects. After signing the informed consent form and verifying the inclusion criteria (participants in the ANRS EP46 NOVAA study), the subjects are included in the study: <ul style="list-style-type: none"> • 40 HIV-positive subjects enrolled in the Infectious Diseases Department • 20 HIV-negative subjects enrolled in the Travelers' Clinic Evaluation will take place at M156 (+/- 18 months) , i.e., more than 10 years after the vaccine injection.
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Publication References	
Study Type	Category 2, multicenter interventional study comparing two parallel groups of 40 HIV-positive and 20 HIV-negative subjects included in the ANRS EP46 NOVAA study.
Primary Objectives	To determine vaccine responses by measuring neutralizing antibody titers using long-term PRNT neutralization tests in participants of the ANRS EP46 NOVAA study, PLHIV and vaccination-naïve controls, 156 months after primary yellow fever vaccination
Secondary objectives	-To determine vaccine responses by measuring neutralizing antibody titers using AcN 400 pseudo-type neutralization tests. -Determine the clinical and biological factors predictive of a sustained vaccine response.
Optional: Link to the	

research website	
Inclusion criteria	<ul style="list-style-type: none"> • Subjects included in the ANRS EP 46 NOVAA study: <ul style="list-style-type: none"> - 40 HIV-positive subjects from infectious disease clinics and travel medicine centers at Saint-Louis, Cochin-Pasteur, and Bichat hospitals (on HAART for at least one year and with no changes in the 3 months prior to the pre-inclusion visit, CD4 >^{350/mm³} and a viral load < 50 copies/mL for at least 6 months). - 20 HIV-negative subjects from the travel medicine clinics at Saint-Louis, Bichat, and Cochin-Pasteur hospitals. • Subjects agreeing to be followed according to the protocol's terms. • Subjects enrolled in or eligible for Social Security coverage. • Signature of the informed consent form.
Exclusion criteria	<ul style="list-style-type: none"> • Not willing to participate in long-term follow-up • Subjects under legal guardianship, conservatorship, or judicial protection.
Primary outcome measures	<i>Immunovirological:</i> At M156, neutralizing antibody titers will be determined by PRNT
Secondary endpoint	<ul style="list-style-type: none"> • Immunovirological: At M156, neutralizing antibody titers will be determined using the AcN 400 pseudotype. • Clinical and biological factors predictive of a sustained vaccine response.

Summary

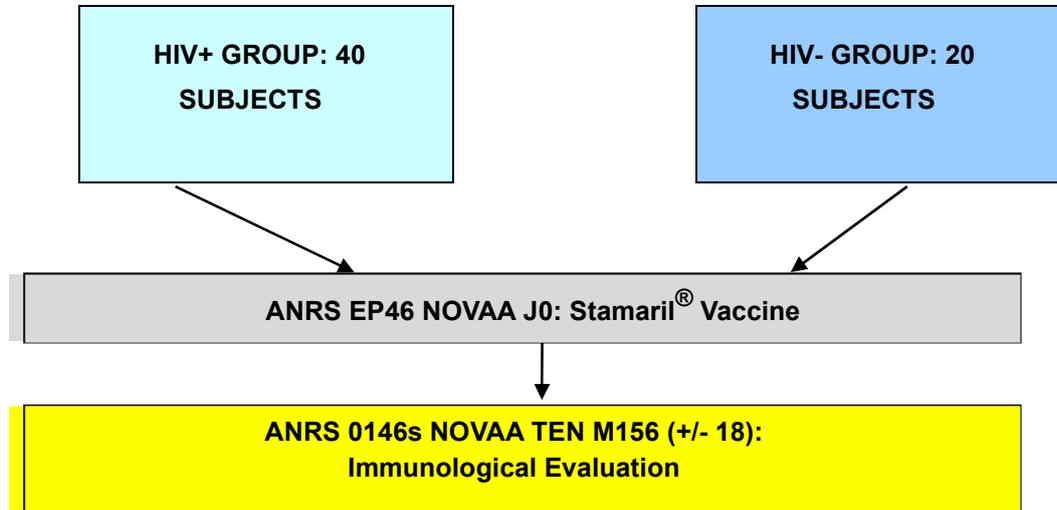
A – Study methodology and type of data and/or samples collected

B – Terms of access to the collection

A – Study methodology and type of data and/or samples collected

Data and samples collected	Biobanks	blood
	Data	Clinical and biological

Study design:



Schedule for participant follow-up in the study

Date (D: day / M: month)	ANRS EP46 NOVAA	ANRS 0146s NOVAA TEN
	D0	M156 ± 18M
	Stamaril®	
Signature of consent		*
Clinical examination, HR, Weight, T, BP	*	*
Recording of vaccinations, travel history, comorbidities		*
Lab tests	*	* 1
Humoral immunity		
PRNT	*	*
WN pseudotypes	*	*
Biobank		
Plasm library (P) + cell library	*	P

B – Terms of access to the collection

1- Project submission: **via the sample request form on the website**

2- Project evaluation: **scientific committee or independent experts**

3- Provision of the collection: **final decision by ANRS MIE management or the scientific advisory board**

Contact email address for submitting your project: **biobanque@anrs.fr**