



VIC - Centre d'Immunothérapie et de Vaccinologie
Service d'Immunologie & d'Allergie, Département de Médecine

Centre Hospitalier Universitaire Vaudois
CH - 1011 Lausanne, Suisse
www.immunologyresearch.ch

EuroVacc 03/ANRS Vac 20: A phase I/II trial to compare the immunogenicity and safety of 3 DNA-C prime followed by 1 NYVAC-C boost to 2 DNA-C prime followed by 2 NYVAC-C boost

This phase I/II clinical trial is to compare two immunization strategies using two experimental vaccines for the prevention of HIV infection, DNA-C and NYVAC-C. These vaccines are based on HIV subtype C, which is prevalent in China, India and sub-Saharan Africa, and constitutes more than 50 percent of the new HIV infections worldwide.

The primary objectives of the study are to compare the immunogenicity and safety of three DNA-C prime and one NYVAC-C boost regimen to two DNA-C prime and two-NYVAC-C boost in healthy volunteers at low risk of HIV infection. 140 volunteers will be enrolled and randomised to either of the above arms. The immunogenicity of the 2 different prime-boost regimens, in particular their ability to generate HIV-specific cell-mediated immune response to HIV, will be compared in order to evaluate which strategy provides the best results. All volunteers, male or female, should be aged between 18 and 55 years, HIV-negative and at low risk of infection.

This study will take place in 4 countries (Germany, Switzerland, UK and several sites in France) and possibly in South Africa. The EuroVacc Foundation will act as the sponsor of the EuroVacc 03/ANRS trial for sites in Germany, Switzerland, UK and the “Agence National de Recherches sur le Sida (ANRS)” in France will act as the sponsor for French sites and as the Legal Representative of the Eurovacc Foundation in the EU member States.

Development background

The vaccine candidates for the trial - DNA-C and NYVAC-C - were developed within the European Vaccine Effort against HIV/AIDS network. NYVAC-C (a vaccine candidate based on poxvirus) was manufactured by sanofi pasteur - the vaccine division of Sanofi-Aventis - and has already been evaluated in two phase I studies (EuroVacc 01 and EuroVacc 02) at the clinical centres of Lausanne and London. The completed phase I studies showed that the NYVAC-C is safe and immunogenic. The DNA-C vaccine was developed by University of Regensburg and manufactured by Cobra Biomanufacturing Plc. DNA-C, first injected during the phase I study EuroVacc 02 was safe and well tolerated. The combination of 2 DNA-C vaccinations followed by 2 NYVAC-C vaccinations evaluated in this study was also shown to be safe and has induced very promising immune response. There is now a need to identify the best regimen for the combination of DNA-C as a prime and NYVAC-C as a boost. Data from recent studies in humans are suggesting that 3 vaccinations with DNA as a prime induce a better immune response than only 2 vaccinations. The aim of the Eurovacc 03/ANRS Vac 20 will be to evaluate this hypothesis for the DNA-C+NYVAC-C combination.