What is ISS P-002: short study description

Title of study:

A PHASE I, OPEN LABEL, SAFETY AND IMMUNOGENICITY PREVENTIVE VACCINE TRIAL BASED ON THE ASSOCIATION OF RECOMBINANT HIV-1 TAT AND ENV PROTEINS IN HIV UNINFECTED HEALTHY ADULT VOLUNTEERS

Description

The ISS P-002 study is directed at evaluating the safety and the immunogenicity of the preventive vaccine based on the recombinant HIV-1 biologically active Tat and V2-deleted Env proteins administered in association in healthy, HIV-uninfected, adults volunteers, compared to the Env or Tat proteins alone. The HIV-1 Tat protein is a regulatory protein produced early after viral infection that has a key role for the replication of the virus, for its transmission from cell to cell and for the progression of the disease. Env is a protein that constitutes a portion of the external coating (called the envelope) of the HIV-1 virus that has been modified in order to increase its ability to stimulate an immune response against critical Env domains. Blocking of these critical Env domains by the specific antibodies induced by the vaccine is expected to prevent virus entry into target cells and, therefore, the infection.

The Tat and Env proteins have been already tested in humans as single vaccines against HIV infection and both have been shown to be safe and well tolerated. The combination of the two products, which is going to be evaluated for the first time in humans in this preventive trial, has been tested in several animal models and was also shown to be safe, well tolerated, and effective in protecting form the infection (monkeys).

The ISS P-002 study is open label, thus every participant will be informed on the characteristics of the product which is administered to him/her. The Tat/Env combined vaccine (or the single products) will be injected 3 times by the intradermal route, followed by 2 additional intramuscular boosts. The study does not foresee the administration of placebo.

The requirements to participate in the trial are specified in the clinical protocol. The satisfaction of such requirements (inclusion and exclusion criteria) makes it possible to participate in the trial. Such criteria have been determined by the researchers and doctors of the experimental team to the purpose of facilitating the interpretation of the experimentation results.

The ISS P-002 trial will enjoy the support of three independent advisory boards (*International Advisory Board, Data Safety Monitoring Board, Community Advisory Board*).

For results about the effectiveness of the preventive vaccine we will have to wait until the end of the Phase II/III clinical trials, which will be consequent to a positive result of the Phase I study. It is key to remember that we do not know whether the vaccination will prevent the transmission of the virus, therefore the participants to the experimentation will have to continue avoiding any risky behaviour (unprotected sexual intercourses and using contaminated needles).

For any information about the study you can refer to the toll free AIDS telephone of the Istituto Superiore di Sanità (800 861 061, from Monday to Friday between 1 p.m. and 6 p.m.) and, if you are interested in joining the study, it is possible to get in contact with the participating Clinical Centers to program the preliminary interview and the evaluations needed to assess the suitability to trial participation.

You can also visit the websites http://www.iss.it/aids/ and http://www.hiv1tat-vaccines.info for information on how to contact participating Clinical Sites.