FUNDACIÓN LUCHA CONTRA EL SIDA
Y LAS ENFERMEDADES INFECCIOSAS

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CLINICAL STUDY PROTOCOL

KANELA

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ENSAYO CLÍNICO PROSPECTIVO, ABIERTO Y ALEATORIZADO, SOBRE LA SEGURIDAD HEPÁTICA DEL TRATAMIENTO ANTIRRETROVIRAL QUE INCLUYE KALETRA VS NEVIRAPINA EN PACIENTES COINFECTADOS VIH/VHC. ESTUDIO KANELA

[PROSPECTIVE, OPEN AND RANDOMIZED CLINICAL TRIAL ON THE LIVER SAFETY OF ANTIRETROVIRAL TREATMENT THAT INCLUDES KALETRA VS NEVIRAPINE IN HIV/HCV CO-INFECTED PATIENTS. KANELA STUDY]

Due to the small number of patients included in the study, 4 in the control group and 5 in the

the experimental group (one of whom withdrew consent before starting the study treatment) it will not be possible to draw any conclusions.

To assess the evolution of hepatic fibrosis in HIV/HCV co-infected patients treated with nevirapine and compare this evolution with patients who substitute nevirapine for lopinavir/ritonavir, it was necessary to obtain a sample of a minimum of 100 patients.

By not having achieved the planned N (Number of participants), it will not be possible to assess the evolution of fibrosis hepatic in patients treated with nevirapine and its comparison with patients in lopinavir/ritonavir treatment.

This trial has been terminated early because of the impossibility of obtaining a sample of "n" equal to that specified in the protocol of the rehearsal. The inclusion period of the trial was 6 months, and it was intended to include 100 patients. Finally, the inclusion period has been extended to 10 months, achieving an N=9.