

Study Identification

ClinicalTrials.gov ID: NCT03119025

Unique Protocol ID: IFCI-04/10/2015

Brief Title: Autologous Dendritic Cell Vaccine for Treatment of Patients with Chronic HCV-Infection

Official Title: Safety/Efficacy of Vaccination with Autologous Dendritic Cells Pulsed with Recombinant HCV-Antigens (Core and NS3) for Treatment of Patients with Chronic HCV-Infection

The protocol was approved by the Ethics Committee of the Institute of Fundamental and Clinical Immunology (approval number: no 88, 04/10/2015)

April 10, 2015

Statistical Analysis Plan

Data will be analyzed using Statistica 9.0 software. The results of statistical analysis will be presented as median and interquartile range. The Mann–Whitney test (for independent samples; p_U) and Wilcoxon test (for dependent samples; p_W) will be applied, and differences with p less than 0.05 will be considered statistically significant. Correlation analysis will be conducted by Spearman's rank-order correlation (R_S).