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Open-label trial of therapeutic immunization with oral V-5 Immunitor (V5) vaccine in patients with chronic hepatitis C

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Summary

We evaluated whether V-5 Immunitor (V5) – tableted therapeutic bivalent vaccine comprising heat-inactivated HCV antigens from pooled blood of HBV- and HCV-infected donors – may produce clinical benefit through induction of oral tolerance and reduction of immune-mediated liver injury. Once daily dose of V5 was administered *per os* to 10 patients with chronic hepatitis C in an open-label study that lasted 1 month. Every patient who entered the study had elevated liver enzyme levels, which at the end of study have decreased in 100% of analyzed patients. The reduction was highly significant,

from 157.7 ± 73.4 to 49.9 ± 43.8 U/L ($P = 0.0013$) and 147.0 ± 79.2 to 58.7 ± 56.6 U/L ($P = 0.0132$), for ALT and AST, respectively. The AST/ALT ratio has improved from 0.93 to 1.18 ($P = 0.00058$) indicating the reversion of progression to cirrhosis. None of intent-to-treat patients who were anti-HCV antibody positive at study entry, became negative after 1 month on V5 ($P = 0.998$). All patients, except one, reported complete recuperation from hepatitis C-associated clinical symptoms present at baseline ($P = 0.0016$) with Mantel Haenszel's odds ratio 9.4 ($P = 0.0021$) at 95% confidence interval: $2.7 < OR < 476.3$. No adverse events were observed at any time. The favorable biochemical and clinical responses have been observed in a small number of individuals for a limited time period. Larger scale and longer studies are needed to confirm our preliminary observations suggesting that V5 is safe and effective means for immunotherapy of chronic hepatitis C.

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Keywords

Alloimmunization; Liver function test; Therapeutic vaccine; Immunomodulation; *Per os*

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