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Abstract

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Thymalfasin for the treatment of chronic hepatitis B.

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Abstract

Chronic hepatitis B virus infection is a serious problem because of its worldwide distribution and possible adverse chronic sequelae, such as cirrhosis and hepatocellular carcinoma. Chronic hepatitis B infection is a dynamic state of interactions between the virus, hepatocyte and host immune response. Interferon-alpha and direct antiviral agents, such as lamivudine (Epivir, GlaxoSmithKline), are effective in the therapy of chronic HBV infection but the efficacy is far from satisfactory. Thymalfasin (thymosin alpha1; Talpha1, Zadaxintrade mark, SciClone Pharmaceuticals, Inc.) is a 28-amino acid polypeptide produced synthetically but originally isolated from thymosin fraction 5, a bovine **thymus extract** containing a number of immunologically active peptides. In vitro studies have shown that Talpha1 can influence T-cell production and maturation, stimulate production of Th1 cytokines such as interferon-gamma and interleukin-2, and activate natural killer cell-mediated cytotoxicity. Seven randomized controlled studies on Talpha1 monotherapy in patients with chronic hepatitis B showed that 6 months treatment with Talpha1 (1.6 mg twice-weekly) resulted in a significantly higher sustained response rate than untreated controls. The benefits of Talpha1 therapy is usually not immediately apparent during therapy. There is a trend for complete virological response to increase or accumulate gradually after the end of thymosin therapy. The results of Talpha1 and interferon combination therapy in two open-label trials were also promising. In terms of the mechanisms of action, a combination of Talpha1 and nucleoside or nucleotide analogs is a logical approach in the control of chronic HBV infection and a randomized control study is ongoing.

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