

Clinical Trial on Chronic Hepatitis B by Using Vitalliver Suppository

The clinical trial of the Chronic Mutational Hepatitis B was carried out by Dr. Jiang Nan in Chengdu, Sichuan, China and the study report is shown below.

The Evaluation of terminal and persistent responses on Vitalliver suppository therapy on Chronic Hepatitis B carriers with Pre Core Mutation using HBV DNA quantitative fluorescence PCR assay

No. of Subjects (N): 25

Age Range: 16-65

Inclusion Criteria: Xian Conference Standards, 2000

Dosage: Twice daily, one suppository per time for 6 weeks.

Measurement

(1) HBV DNA copies/ml after the 6 weeks therapy of Vitalliver suppository.

(2) Persistent HBV DNA copies/ml, after stop-using Vitalliver suppository for 6 months.

Criteria of Therapeutical Effect:

(1) If HBV DNA count $< 10^4$ copies/ml, considered to be "Effective".

(2) If HBV DNA count is reduced by at least 2 logarithmic order, considered to be "Improved".

(3) If HBV DNA count is unchanged, or it is reduced by less than 2 logarithmic order, considered as "Not Effective".

Classified into five grades: Definitely Related; Probably Related; May be Related; Probably Not Related, Definitely Not Related

Results

(1) Terminal response after 6 months therapy

, HBV DNA count $< 10^4$ copies/ml, 21/25 (84%)

HBV DNA count $> 10^4$ copies/ml, 4/25 (16%)

(2) Persistent response after treatment:

HBV DNA count $< 10^4$ copies/ml, 23/25 (92%)

HBV DNA count $> 10^4$ copies/ml, 2/25 (8%)

Conclusions:

(1) The terminal response rate of Chronic HBV carriers with Pre Core mutation by using Vitalliver suppository for six weeks is 84%.

(2) The persistent response rate of Chronic HBV carriers with Pre Core mutation after stop-using Vitalliver suppository for six months is 92%.

Evaluation:

- (1) After the chronic HBV carriers with Pre Core mutation used Vitalliver suppository for six weeks, their viral load of serum were significantly decreased and both terminal response rate and persistent response rate are good.
- (2) When comparing terminal response with persistent response, persisting response rate (92%) seems to be higher than terminal response rate (84%). It is suggested that Vitalliver suppository may have continued suppression of HBV virus duplication even after stop-using the drug.

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