

Hepatitis C Viral Infection

There are at least six viruses known to cause liver disease. The Hepatitis C viral (HCV) infection is the most common blood-borne viral infection in the United States. The prevalence of HCV is estimated at 1.8% of the American population (4.5 million people), of whom 2.7 million are chronically infected.

The FDA treatment of Hepatitis C is centered around combination therapy with Interferon Alfa and Ribavirin. Combination therapy with these two agents yields a sustained virologic response of 54% overall (sustained response = at least six posts post therapy).

Many herbs such as milk thistle, licorice root, ginseng and dandelion leaf have an effect on Hepatitis C, mostly an improvement in liver enzymes. To date, no herb or herbal combination has been shown to affect viral loads in patients infected with the Hepatitis C virus.

A pilot study using Oregacyn P73 Liver Formula and Oreganol P73 was begun in May 2003. Oregacyn P73 Liver is a proprietary blend of spice extracts with an Oreganol P73 base.

Inclusion Criteria:

- Untreated HCV > 18 years old
- HCV RNA PCR > 10,000 copies/ml blood

Study Design:

- Arm One: Oregacyn P73 Liver (3 capsules, three times daily, with meals)
- Arm Two: Oreganol P73 Super Strength (size 00 filled capsule, three times daily)
Oregano P73 Gel Caps (three softgels, twice daily)
- Liver enzymes tested: Week 0, 4, 12, 24, & 52
- HCV RNA tested: Weeks 0, 4, 12, & 52

The preliminary results from the study are shown in Table 3.

Results:

(Table 3)

<u>Patient</u>	<u>ALT Pre Tx</u>	<u>ALT Post Tx</u>	<u>HCV RNA Pre</u>	<u>HCV RNA Post</u>
KK (Oil)	282 (04/96)	23 (11/03)	+5,000,000(04/97)	13,932 (05/03) 446 (11/03)
EFB (OL)	84 (W-4)	113 (W-12) 117 (W-24)	96,000 (W-0)	91,000 (W-4) 770,000(W-12) 250,000(W-24)
FIH (OL)	61 (W-0)	35 (W-4) 41 (W-8) 39 (W-12) 32 (W-20)	192,000 (W-0)	135,000 (W-4) 57,600 (W-8) 67,000 (W-12) 6,600 (W-20)
SMA (OL)		39 (W-4) 40 (W-12)	228,000 (W-0)	193,000 (W-4) 816 (W-12)
MS (OL)	112 (W-0)	112 (W-8) 141 (W-24)	14,909,477 (W-0)	2, 321,626 (W-24)
LL (Oil)	96 (W-0)	52 (W-8)	2,750,000 (W-0)	744,000 (W-8) Pending (W-16)
ND (Oil)	49 (W-0)	Pending	933,000 (W-0)	Pending (W-8)

The preliminary results of this pilot clinical trial demonstrated that Oreganol P73 and Oregacyn P73 Liver Formula are two very active spice extract formulations with anti-viral activity against the Hepatitis C virus in vivo. Six patients have been enrolled in this trial to date, with one patient (KK) being enrolled off-protocol.

Of the six patients enrolled on the protocol, five patients have reportable data (one patient, ND, has lab results pending). Four of the five patients (80%) had a decrease in HCV RNA titers. Three of the five patients (60%) had a corresponding drop in ALT enzymes.

One patient's (EFB) HCV RNA went from a baseline of 96,000 copies/ml to a high of 770,000 copies per ml during therapy, and then began to decrease again by week 24 (to

250,000 copies/ml). The patient also had elevations in ALT and other liver enzymes. This result is not unexpected and is also seen in patients treated with Interferon Alpha. This may in part be attributable to an overtaxed P450 system of the liver, decreased glutathione transferase activity and liver congestion. The patient continues to be on protocol.

Patient KK is a patient with a 25-year history of HCV from a blood transfusion. This patient failed Interferon Alpha therapy and maintained a very high viral count and elevated liver enzymes. The patient was treated off-protocol for 18 months with Oreganol P73 and had a significant improvement in liver enzymes, as well as a decrease in HCV RNA from 5,000,000+ copies/ml to 446 copies/ml. This patient continues to be treated off-protocol, with no reportable adverse events related to prolonged treatment with Oreganol P73.

This pilot clinical trial in patients with the Hepatitis C viral infection demonstrated that Oreganol P73 and Oregacyn P73 Liver Formula are two wild oregano-based spice extracts with antiviral activity against the Hepatitis C virus. The preliminary data from this pilot trial demonstrated that 80% (4/5) of patients with reportable data had a decrease in their HCV RNA titers, some showing a significant drop in viral load. Some of the reported adverse events possibly related to therapy included bloating and insomnia. This study is ongoing, with additional patients being enrolled.

In conclusion, wild oregano and wild oregano-based spice extract formulations exhibit significant antiviral, antifungal and antibacterial activity against a variety of microorganisms. Emerging pilot clinical data has demonstrated that Oreganol P73, Oregacyn P73, Oregacillin P73 and Oregacyn P73 Liver Formula are potent spice extracts with not only antiseptic activity, but strong antioxidant activity as well. Oregacillin P73 has activity against *Helicobacter pylori* in vivo, with the most effective dose and duration of therapy yet to be determined. Oregacyn P73 Liver Formula and Oreganol P73 are two very active antiviral spice extract formulas against the Hepatitis C virus, with preliminary results indicating that 80% of patients treated had a decrease in HCV RNA viral loads.