

Amyotrophic Lateral Sclerosis (Lou Gehrig's Disease)

Amyotrophic Lateral Sclerosis (ALS) is a progressive neuromuscular condition characterized by weakness, muscle wasting and increased reflexes. ALS involves degeneration of upper and lower motor neurons. Fifty percent of patients die within 18 months after diagnosis, and only 10% of patients live longer than 10 years.

A human clinical pilot trial was recently conducted to assess the benefit of using Oregacyn P73 and Oregano Juice in patients with Amyotrophic Lateral Sclerosis (ALS). All patients in the pilot trial had a diagnosis of Amyotrophic Lateral Sclerosis with varying degrees of symptoms and disease progression.

The study included 18 patients from the United States and Canada and divided patients into three treatment arms:

Arm A: Oregacyn P73 (1 capsule, twice daily)

Arm B: Oregano Juice (1 tablespoon, twice daily)

Arm C: Oregacyn P73 (1 capsule, twice daily) + Oregano Juice (1 tablespoon, twice daily)

Treatment duration: 90-120 days

The rationale for using the spice extracts was to assess whether the antiseptic properties and potent antioxidant activities had any effect on symptoms associated with ALS.

Patients evaluated their symptoms via a biweekly questionnaire, rating their symptoms on a 1-10 scale.

Study Results:

- 07/18 reported an improvement in their symptoms
- 06/18 reported their symptoms remained the same
- 05/18 reported a worsening of their symptoms

Of those patients reporting an improvement in their symptoms:

- Three patients reported a 20%, 50% and 70% improvement in their breathing
- One patient reported a 70% improvement in swelling
- Two patients reported a 50% and 60% improvement in pain
- Two patients reported a 20% and 50% improvement in swallowing

This pilot study demonstrated that spice extracts may have some beneficial effect on symptoms associated with Amyotrophic Lateral Sclerosis. These are preliminary results, and further study in this patient population using varied doses and a longer duration of treatment with spice extracts may be of benefit in managing symptoms.

Helicobacter pylori Infection:

Helicobacter pylori (H.pylori) is a spiral-shaped bacterium found in the gastric mucous layer or adherent to the epithelial lining of the stomach. H. pylori causes more than 90%

of duodenal ulcers and up to 80% of gastric ulcers. Current FDA treatment of *H. pylori* consists of multiple courses of combination antibiotics (double and triple antibiotic regimens), with response rates ranging from 61-94% at the end of therapy. Treatment relapse is common and combination antibiotic therapy is associated with adverse events and drug resistance as well as interference with nutrient absorption.

A clinical human study using the Oregacillin P73 blend in patients with untreated *Helicobacter pylori* was begun in April 2003. The pilot clinical trial had a projected accrual of ten patients with a positive urea breath test or positive serology. The objective of the study was to assess the activity of Oregacillin P73 in vivo and the tolerance of a spice extract blend in the treatment of patients with untreated *H. pylori*.

Study Design:

In the first phase of the trial, five patients received Oregacillin (3 capsules, twice daily for 14 days). In the second phase of the trial, five patients are scheduled to receive the same dose of Oregacillin for 14 days, but would be eligible for a second and third course based on response. The first phase of the trial is now complete.

Results:

(Table 2)

<u>Patient #</u>	<u>UBT Pre</u>	<u>UBT Post</u>	<u>% Change</u>
One	102.3	96.0	9.4 % Decrease
Two	9.9	12.8	29.0 % Increase
Three	15.4	3.8	86 % Decrease
Four	14.8	12.6	15 % Decrease

Conclusion:

- In this pilot dosage study, three of four patients in the trial had a positive response to therapy (reduction in bacteria count)
- Oregacillin P73 had activity against the *H. pylori* bacteria in vivo after a 14-day course of therapy (in three out of four patients)
- A longer duration of therapy with Oregacillin P73 appears to be indicated and may be required to exert a greater killing effect against the bacterial infection
- All four patients tolerated the 14-day regimen well, without adverse events, reductions in dosage or gastrointestinal upset
- The most effective dosing schedule of Oregacillin P73 needed for the complete eradication of *H. pylori* (in vivo) has not been determined

Phase two of this clinical trial will allow for patients to receive up to six weeks of therapy with Oregacillin P73 and will allow for the addition of Oil of Oreganol P73 to the regimen as a means of assessing the synergy between the various spice extracts.