

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.