# Lyme Study September 2006 - December 2006

#### **Study Proposal**

Ten Lyme patients who had failed to improve with pharmaceutical treatments involving antibiotics and I.V. treatments were chosen to begin an alternative treatment for chronic Lyme disease. In this pilot Lyme study the ten patients in the natural treatment group will be compared with at least ten other patients of approximately the same degree of illness who continue to receive conventional therapy. Can alternative therapies make a difference in Stage 3 Lyme Disease with a uniform comprehensive natural protocol?

# **Principle Investigators**

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### **Medical Review Board**

William Keller Ph D Hugo Rodier M.D.

## Product Support, R & D and product Technical Data Antimicrobial Support

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#### **Allimax Nutraceuticals**

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#### **Nutritional Support**

Nature's Sunshine Products Inc.

Use strict pharmaceutical guidelines to produce each of their products
Based out of Provo, Utah N.S.P was awarded Manufacturer of the Year in 2002 by Nutritional
Outlook. They are largest the industry in nutritional supplements celebrating their 35<sup>th</sup> year,
since they started the industry of encapsulating herbs in 1972.

# Research Program

Research Investigators and Medical review board agreed to the following guidelines to attempt to change to terrain of the cell and the body. The key to improving chronic disease is meeting the needs of a single cell. If you give the body the nutrients a single cell needs to function normally, the body often has the power to heal itself. Spirochetes have a tremendous ability to sense the make-up of the environment they live within (the cell). They can sense chemicals they need for food especially sugars. For this reason the nutritional changes, pH balancing and supplements were included in this study.

1. HYDRATION— All "treatment patients" were asked to drink at least 50% their body weight in ounces daily of purified water, not to exceed 100 ounces. Water counts for approximately 70% of total body weight and is the foundation of all life. Reduced water causes every cell to function improperly, causing dehydration. Thus the cell can not flush out waste. Soda and coffee will not substitute for good purified water but creates acid conditions. Everything that is acidic is an electron stealer creating inflammation.

2. **DIETARY CHANGES** - All were given a Blood Type Diet along with a Low Glycemic Diet. Grains, Fruits, and Vegetables according to their blood type. Agglutination or cells clumping together happens when we eat foods not compatible with our blood type.

- A.) The seven most allergenic foods were eliminated:
  - 1. wheat,
  - 2. sugar,
  - 3. peanuts,
  - 4. dairy,
  - 5. soy,
  - 6. shellfish,
  - 7. corn

Replacing these with Hemp bread, Xylitol, Stevia, nuts for blood type, goat's milk or almond milk, cold water fish and grass fed beef.

B.) DRINKS-All treatment patients were asked to eliminating caffeine and sodas, and use herbal teas and drinking purified water with lemon.

"Eliminating or reducing coffee, tea, and alcohol as it blocks zinc and selenium. Zinc is one of the most important elements in the body without zinc you can't make stomach acid or digest your food properly. Without zinc you can not make neurotransmitters like serotonin, dopamine, norepenephrine, and epinephrine." Jerry Tennant M.D. Tennant Institute for Integrative Medicine "How the Body is designed to Work" p.7

- C.) GOOD FATS are very important daily, as they make healthy cell membranes. All were asked to use extra virgin olive oil also organic eggs and avocadoes daily, nuts, especially walnuts. NO hydrogenated, peanut or corn oils as they create free radicals and 'steal' electrons from the lipids in our cell membranes and cause cell damage.
- D.).Low Glycemic foods –All treatment patients were asked to eliminate sugar, honey, maple syrup, aspartame and any artificial sweeteners, instead they used <u>Stevia or Xylitol</u> (natural sweeteners). "Foods that have a high glycemic index turns to blood sugar very quickly after we eat them. When we eat foods that have a high glycemic index, our blood sugar rises rapidly. This is followed by an overproduction of insulin. When insulin levels get high enough, then our bodies sugar drops rapidly until we eat again. This roller coaster of insulin and blood sugar causes sugar cravings and prevention of fat burning, decreased metabolism and worst of all Insulin Resistance. This nutritional program was designed to improve your overall health; however weight loss is a beneficial effect." (Dr. Hugo Rodier Medical Review Board.)

By reducing the sugar and blood sugar spikes the spirochetes are forced to pleomorphically change size and form.

# 2. Nutritional Support

A) Enzymes (FOOD ENZYMES) 5 daily

Each tablet will digest 30 grams of protein, 30 grams of carbohydrates and 20 grams of fat. Digestive enzymes improve absorption of vitamins and minerals, helps maintain normal pH levels and stimulates the growth of healthy intestinal bacteria. The most important action of enzymes is aiding in elimination of toxins and neurotoxins created by B. Burgdorferi. American Journal of Clinical Nutrition of 2004 study found that digestive enzymes help reduce homocysteine levels a dangerous toxin that is connected to heart disease, common in chronic Lyme patients.

B) Vitamins/Minerals/Amino Acids (VITAWAVE) 1 oz. daily

Vitawave provides at least 100% of 17 essential vitamins and minerals in a base of herbs. Amino acids, plant-derived trace minerals and helpful nutrients including lutein also the glutathione precursor ALA (Alpha Lipoic Acid) important from detoxifying from heavy metals) Symptoms of heavy metal toxicity may overlap symptoms of Chronic Lyme disease and associated co-infections. 16th International Scientific Conference on Lyme Disease and other Tick borne Disorders. May 2003 U.S.A. (The Journal of the American Medical Association). Study states "Most people do not consume an optimal amount of all vitamins by diet alone pending the strong evidence of effectiveness from randomized trials it appears prudent for all adults to take vitamin supplements."

# C) Antioxidants (THAI-GO JUICE) 2 oz daily

Is a blend of botanical ingredients rich in natural antioxidants magosteen's powerful antioxidant also have antibiotic, antifungal, anti-inflammatory actions as well as histamine blocking properties. Wolf berry fruit is used in China as blood, liver and kidney tonics. Sea Buckthorn and Green Tea enhances the immune system. Grape skins, blueberries and granny smith apples contain powerful antioxidants and enhance the taste.

# D) Fiber(EVERYBODY'S FIBER) 2 Tbs. daily

This combination mucilaginous herbs blends soluble fiber with insoluble fiber to soothe and heal the gastrointestinal tract also we recommend fiber so that the dead microorganism can be carried out of the colon easier. Mucilaginous includes Slippery Elm, Marshmallow and Asparagus. Relaxing herbs Chamomile, Peppermint and Fennel improve digestion and reduce gas Flax meal provides bulk preventing the reattachment of parasites to lower bowel wall.

# E) Essential Fatty Acids (SUPER OMEGA 3 W/ DHA) 3 daily = 1,000mg

Fish Oil is the most important component to be observed in an alternative treatment of Lyme's disease. Fatty Acids make of 80% of the brain and are necessary for every cell of the body. The cell wall membrane is made of fat, it also controls the cell which is considered the "brain". The liver is responsible for the production of bile which breaks down fat, the liver contains 35,000 sq, meter (about the size of 7 football fields) these membranes are made of fats. If you don't eat enough good fats or eat fats that have been processed they are similar to plastic the cell membrane becomes stiff and doesn't work correctly.

F) Probiotics (BIFIDOPHYILUS) 3 daily for 15 Billion of friendly Bacteria Friendly bacteria should naturally inhabit your intestinal tract and help break down food. Aid digestion, enhances your immune system, provides absorption for B12. The gut has been called the second brain and is responsible for many of our neurotransmitters." THE SECOND BRAIN" Author Most people with Lyme disease have emotional stress and anxiety issues.

Antimicrobial Treatment – Allisure® AC-23 stabilized allicin each patient started on 1 cap. 3 X a day and increased to 2 caps. 3 X a day or 3 drops 3 X a day and increased to 10 drops 3 X a day.

Some treatment patients had to decrease because of the Herxheimer healing crisis (caused by toxins released by the large number of dead spirochetes and co-infections being eliminated during the initial part of the treatment)

Allimed is the result of a patented process which produces real allicin liquid. It is the first health food supplement to deliver real 100% stabilized allicin. This is the key ingredient or mother substance from fresh raw garlic that contains the beneficial **allicin** derivatives that also contribute to good health. **Allimed® Allisure® AC-23** capsules contain 450mg of our highest potency freeze dried stabilized allicin powder.

Studies have been proven against multi-drug resistant species of MRSA, Methacillin resistant Staphylococcus Aureus, VRSA and GRSA bacteria, ECC MID Conference April 2005 Copenhagen, Denmark

Allisure® AC-23 stabilized allicin is also capable of destroying a wide range bacteria and fungal infections. Published work shows excellent activity against *Staphylococcus*, Candida albicans, Streptococcus Species, Escherichia Coli, Salmonella Species and Helicobacter Pylori.

Allisure® AC-23 stabilized allicin has been proven to treat the common cold virus in the only 140 person double blind placebo clinical trial published recently peer revered

American Medical Journal: Advances in Natural Therapy, vol. 18, # 4 July/August 2001 pgs. 189-194

#### **Testing Procedures**

- 1. SELF HEALTH ASSESSMENT All ten treatment patients in the Pilot study were asked to quantitate on a scale of 1 10 the degree of severity of their 10 most problematic symptoms, every 2 weeks through 12 weeks
- 2. SF8 FORM Each patient also filled out on each visit an SF8 form (which is a validated historical questionnaire developed by the Medical Outcomes Trust of Boston)
- 3. PH TESTING By using a litmus paper which measures the concentration of positive charged ions in your body fluid. The more positive charged hydrogen ions present the more acidic. The fewer the hydrogen ions present the less acid. The pH of saliva and urine was taken every 2 weeks on an empty stomach.

The average pH of saliva on treatment group was 7.0 average pH of urine was 5.5. At the end of the study average saliva was 6.4 and average urine was 6.2.

Our bodies have an internal environment, which is called our biological terrain and is the interstitial fluid that nourishes the 100-trillion cells in your body. Our biological terrain is based on the composition and quantity of fluids our cells live in, which include blood, lymph, gastric juices etc. When these fluids are in proper balance, our cells flourish. When they are out of balance they create an environment conducive to the growth of fungi, bacteria, viruses and parasites. It is important to understand the pH of your blood and is critical to your life and has only a very small degree of tolerance for variation. These fluids serve as indications of the health of our Biological Terrain.

This measurement is called pH or Potential of Hydrogen. The urine is a catabolic process the saliva is an anabolic process. This measurement will indicate the Acidity or Alkalinity of your Terrain. Specific pH levels are necessary for optimum digestion and absorption. Ideally the pH of saliva should average 6.5 and the urine will fluctuate between, 6.0 – 7.0 Prior to an immune dysfunction there is a pH imbalance to reflect this condition.

4. Refractometer (sugar) – A refractometer is used for this test since it records all the sugars in the urine (Blood sugar only record glucose). It is considered the fuel gauge or amount of possible energy available. The sugar reading expresses the ability to digest and store sugar properly. The optimum maximun number, at least 3 hours after a meal should be 1.5. This represents the amount of dissolved solids in the form of complex and simple sugar. The units are expressed in sugar brix. One degree Brix is equal to one percent sugar in the liquid being tested, in this case urine. Therefore the ideal carbohydrate number of 1.5 means 1.5 Brix or 1.5% sugar in the urine sample. If sugar is too high (over 1.5) the body may be insulin resistant and form excess gas, yeast, or fungus. If too low, look for hypoglycemia conditions.

The average SUGAR BRIX of the treatment patients was 3.6 at the beginning of the study, at the end of the study it was 1.9.

- 5. Conductivity A Conductivity Meter was used for this test. It gives vital information about the flow of electricity or voltage in the body. It also can indicate the congestion and stagnation within the body's tissue measured through a small amount of urine. This reading involves the minerals or salts in your fluids. Minerals are needed for many critical actions and reactions in the body; if you put distilled water in a battery it won't hold a charge, so it is with your body. Minerals need to be balanced. Only when your body is depleted of good minerals do heavy metals attach themselves to cell walls. When fluids become congested with too many minerals (toxins) stagnation and congestion may occur which limits the cell's ability to function properly. With too few minerals the body can't hold its electrical charge and can cause cellular dysfunction.
- 6. The average Conductivity of the treatment patients was 9.5 at the beginning of the study, at the end of the study it was 7.4.
- 7. Darkfield Microscopy Through the advent of technological advances in microcopy, new discoveries have been proved by such leading researchers as Royal Rife, Gaston Naessan, Dr. Gunther Enderlein, Dr. Majid Ali, M.D. and many others. In the rapidly emerging field of what is known as live cell analysis an understanding of biology as a wholelistic science has emerged. Health imbalances in the body may be averted by observing the state of ever-present floras found in the blood and by correcting the milieu that allows the floras to remain in the regulatory forms or to move into pathogenicity. Or conversely, to be reduced from pathogenic forms back down to regulators. These observations are made in what is known as **Darkfield** Microscopy. Examinations of live blood in a darkfield are valuable for recognizing imbalances in the body and for tracking the progression toward improvement.

"Under Darkfield Microscopy when the red blood cells are crushed the intercellular stealth pleomorphic Lyme bacteria can be seen in these Lyme patients."

The majority of the treatment patients had:

Erthrocyte Aggregation and Rouleau - red blood cells clumped or stacked together. Fibrin -congestion in the circulatory system and is associated with blood clotting disorders. Poikilocytes - Free radical damaged or deformed RBC's with appearance of bottle caps. Many of the white blood cells were immobile/non-viable.

At the end of the study the majority of the treatment patients the RBC's were negative charged (or not clumping) white blood cells were Phagocytic/Viable very little or no Fibrin and Poikilocytes were gone. When the RBC's were crushed the intercellular Lyme bacteria sprichetal form and cystic form were greatly reduced. The darkfield reflected the positive results that the treatment patients were experiencing.

Biological Terrain is not a new concept but was part of a great debate in the early 1800's. The argument that changed the course of medicine was Louis Pasteur who had the opinion that non-changeable microbes caused disease (monomorphism) on the other side was Antoine Bechamp who stated that the microbe changed according to Biological Terrain. Not until his deathbed did Pastuer change his mind. "The microbe is nothing the terrain is everything" Unfortunately the road was paved for the Germ Theory and it was too late for medicine to turn around. Maintaining the proper balance in the body's ph (or Biological Terrain) can positively affect all major body systems. A Lyme patient with a strong immune system will be able to defend himself against outside invaders. The fact is that many people are bitten by ticks and mosquitoes and don't have health problems that are associated with Lyme disease.