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Laboratoratory Project ID# R10785

Hydrolyzed Egg Membrane

Millions of adults in North America alone have a medical condition relating to joints and/or connective tissues, osteoarthritis, fibromyalgia and lupus. Osteoarthritis alone most common form of arthritis, more so as one ages. The options available to treat the symptoms associated with arthritis, joint deterioration, and other related diseases/conditions are limited and with side effects. The treatment options available alleviate the associated symptoms (pain, inflammation) connected with the diseases. The majority of past/present treatments (Acetaminophen, ASA, Cox 2's, NSAIDS, narcotics, steroids) have had limited success and some varying degree of side effects.
This Hydrolyzed Egg Membrane is a protein characterized by a developmentally advanced proportion of collagen that is effectively matched to skin. It elevates the fibroblasts activity and promotion, stimulating their growth and strengthening the matrix. Fibroblasts are morphologically heterogeneous with diverse appearances depending on their location and activity. The location and timing of cellular differentiation is stringently controlled for adequate organ formation.
A fibroblast is a type of cell that synthesizes the extracellular matrix and collagen. Fibroblasts make collagens, glycosaminoglycans, reticular and elastic fibers, glycoproteins found in the extracellular matrix and cytokine TSLP. Tissue damage stimulates fibrocytes and induces the mitosis of fibroblasts.
The Hydrolyzed Egg Membrane contains several bacteriolytic enzymes and other components that alter the effect of heat-resistant gram-positive and gram-negative pathogens, increasing the skin's ability to withstand a variety of inflammatory processes.
Hydrolyzed Egg Membrane contains very powerful compounds including: a complex of glycosaminoglycans such as glucosamine, chondroitin and hyaluronic acid, elastin, collagen, desmosine, isodesmosine and transforming growth factor-β and other effective compounds. The compounds are proven to be of use for pain management associated with joint disease, due to the distinctive concentration of the potent, natural compounds in the Hydrolyzed Egg Membrane. Therefore in the trial our goal was to examine the effectiveness of this substance on patients with symptoms associated with Osteoarthritis and related inflammatory diseases/conditions which could prove to be far reaching.

Eligibility:

Ages Involved In Study: 21 Years to 80 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No (purpose of trial is to evaluate a substance used to treat diseases/conditions)
Clinical Trial Length: 60 days
Delivery and Type of Substance: Oral – gelatin capsule to be swallowed

- Participants Involved in study: 15 (7 males / 8 females – Added: 3 males / 2 females to make up 20 participants @ 60 days)
- Arthritic patients with confirmed diagnosis, clinically being worked up for or symptoms indicating but not yet confirmed
- Post musculoskeletal injuries with no contributing bone fractures (1 year onward) with current or past history of joint pain and inflammation
- Post bone fracture patients with or without confirmed imaging indicating arthritis but with complaint of pain with or without swelling
- Only Participants that were fully compliant to past medication prescribed by HCP participated in order to achieve a good, negative or unremarkable response
- Past history of medications such as NSAID's and other analgesics a prerequisite for this trial but must have been free and clear for 5 days prior to trials commencement
- clear of all medication for 14 days prior to the start of the trial
- Past history of joint surgery was allowed but must be over 12 months in order to start trial
- All patients in trial were free from allergies and known sensitivities to any substances
- All patients had no gastrointestinal diseases, condition complaints and/or diagnosis by health practitioner

General Inclusion Criteria:

- In good general health with no history of a chronic illness
- Normal liver function tests (ALT, AST, bilirubin)
- Patients with history of anemia (not gross), Elevated Blood chemistry indicating recent elevated ESR or CRP allowed
- Normal renal function tests (creatinine, BUN, urinalysis)
- Must not start any new medications during the clinical trial, if so patient to withdraw
- Patients in trial must be free from all pain control and NSAID's medication during the clinical trial
- Patients all sizes height and weight allowed

General Exclusion Criteria:

- Personal history of cancer, except for non-melanoma skin cancer
- Use of prescribed medications for major chronic disorders currently not controlled by treatment and/or medication
- Confirmed hepatomegaly, hepatitis or ascites diagnosis
- CHF or other chronic cardiac or vascular disorder
- Unwillingness to avoid cruciferous vegetable consumption for the duration of the study
- Women only, positive or suspected pregnancy, if tested or presumed positive during trial for pregnancy patient to withdraw
- Must not be taking any other supplementation such as Glucosamine and Chondroitin
- Using heat and/or cold packs, heating pads, UV Sauna not allowed
- No medical therapy such as chiropractic, physiotherapy, therapeutic massage or spinal decompression therapy
- No past history of Anti-TNF agents or currently taking no "new class anti-inflammatory medications"
- Therapeutic and/or non therapeutic steroidal usage
- Recreational drug usage not accepted

Individual Marked Patient Profiles (Participating In Study):

- 6 patients with past history of confirmed diagnosis for cartilaginous injuries confirmed via imaging/scoping or arthroscopy with or without bloodwork.
- All 15 patients in the trial had moderate to elevated pain/discomfort symptoms over 50% of the day.
- 3 patients had structural bone surgery for traumatic injuries or joint diseases.
- 1 patient had knee replacement surgery but not free from pain and inflammation.
- 1 patient had double knee replacement surgery not free from pain and inflammation – right knee more severe than that of left knee.
- 7 patients were diagnosed with osteoarthritis with multiple areas affected with pain and inflammation.
- Since symptoms progressed at the start of the trial, all patients (100%) claimed that there daily exercise regime had to be modified due to pain upon exertion or exercising.
- 9 patients admitted that there symptoms have drastically altered their daily living lifestyle including family relationships
- 1 patient gave up active sports, baseball in the summer, skiing and hockey in the winter. Patients very distressed about the loss of these activities from his life.
- 4 patients' complained of arthritic inflammatory pain like symptoms in more than 3 parts of their body.
- 1 patient complained of daily cervical arthritic pain like symptoms with rigidity and headaches daily
- 1 patient being a post lower leg amputation > 5 years post surgery complaining of arthritic pain and inflammation daily for 3 years – confirmed diagnosis for osteoarthritis.
- 1 patient with osteoarthritis had also suffered
- 1 participant had arthritis in knees, hip, elbows and lumbar spine, participants activities next to nil
- 2 participants were sought out for uncontrolled sugar levels classed as diabetes 2 for both participants. Both participants were creeping upwards over the past 1-2 months, thus classed as being not well controlled by lifestyle change, diet and medication regimens

Treatment Dosage, Clinical Obervations and Findings

Recommended Dosage (adults):

1 capsule once daily or as directed by a health care practitioner

Medicinal Ingredients per Capsule:

Hydrolyzed Eggshell Membrane - 500 mg

Non-Medicinal Ingredients:

Vegetarian capsule (carbohydrate gum, purified water), vegetable grade magnesium stearate (as a lubricant).

Storage:

For product freshness protect from heat and humidity.

Warnings and Precautions:

Do not use if you have or suspect you may have an allergy or possible reaction to eggs and egg by products.
Please report any adverse/unexpected reactions to your healthcare provider
Keep out of reach of children

Significant Findings and Positive Clinical Responses from Study – Respondents/Testers Input:

- No patients during the trial voluntarily withdrew or were requested to discontinue the Hydrolyzed Egg Membrane capsules.
- The pain scale before commencement of the trial averaged out at 90% for moderate to severe and 10% for low to moderate pain (based on a scale of 1-10 – 1 being the lowest, 10 being the highest),
- 100% of participants could not walk/jog 100 metres without pain occurring in some form.
- 100% of participants at times had pain and inflammation following any activities such as sports or brisk walking.
- 2 senior participants (> 65 years of age) reported that their mobility increased that led to more independence.
- 5 participants with osteoarthritis saw an increase in overall clinical symptoms (pain/mobility/range of motion) by over 75% within 7 days
- 2 participants with osteoarthritis reported less pain, more mobility and better range of motion within 10 days into trial.
- Arthritis and amputee participant noted a decrease in inflammation around the distal area of the amputation within 6 days 45% and by 16 days an overall improvement of 65%.
- Participant with the amputation noticed that a chronic (>3 months) ulceration and dermatitis at the operative site of the stump had healed up to 90% at the end of the 60 day trial
- 2 participants with post bone fractures and arthritic like symptoms at the break sites noted 60% reduction in pain and associated symptoms.
- 1 participant with arthritis and external/internal anatomical damage noted a decrease in site inflammation of 40% and range of motion, pain and general usage increased to 60% by the end of the trial. This individual also had a quality of life improvement by over 50% due to a reduction in her Fibromyalgia.
- 100% of the participants in the trial patients on some form of analgesic or glucosamine and chondroitin found that in general the oral supplementation of Hydrolyzed Egg Membrane was far superior in treating symptoms of pain and inflammation.
- Blood Glucose of uncontrolled diabetes patients equalized to within normal levels after 34 days for one and the other at 40 days on the trial. It should be noted that the uncontrolled diabetes condition of the 2 patients had been that way for >1.5 years.

  Arthritic patient with multiple affected areas (knees, elbows, hip and spine) with extremely limited activity even with aid of a walker significantly improved overall. The participant clearly reported that she could not walk around the indoor shopping mall X 3 days/week. Could also navigate daily functions without assistance, cooking, cleaning the house and personal care.

Optimal Health and Oral pH Testing for Inflammatory Markers:

When the body is alkaline, it converts free radicals to harmless water and oxygen, which helps to maintain energy and vitality. The acid / alkaline balance relates to the chemistry of the body's fluids and tissues as measured by pH. The cells of the body must have a slightly alkaline environment to survive. With a blood pH of 7.365, the cells are in homeostasis and they receive nourishment and release waste with ease. Therefore the entire inflammatory process is suppressed. The body is designed to operate within a very narrow pH range. Optimally the pH should be on the alkaline side, with a blood pH of around 7.365, with a range of 7.34 to 7.45. Even some minor pH fluctuations in either direction creates distress signals in the body, causing various symptoms that start out small and then ramp up as the imbalance continues. Included in these of course is skin eruptions, eczema, inflammation, arthritis, chronic fatigue, weakened immunity, etc. Below we see the base salivary level (acidic) followed by the end of trial salivary pH (alkaline – optimal). The graphs below show the pH average readings of the participants at the start of the trial and the end of the trial. At the start of the trial the pH readings clearly show a more acidic salivary pH indicating a sharp inflammatory state in the body. When we look at Table: 2 graph (termination of trial at day 60), it shows a higher and more balanced pH. This now shows the body returning to levels we see in a healthy adult without disease and the inflammation causative to the disease process.

Table: 1

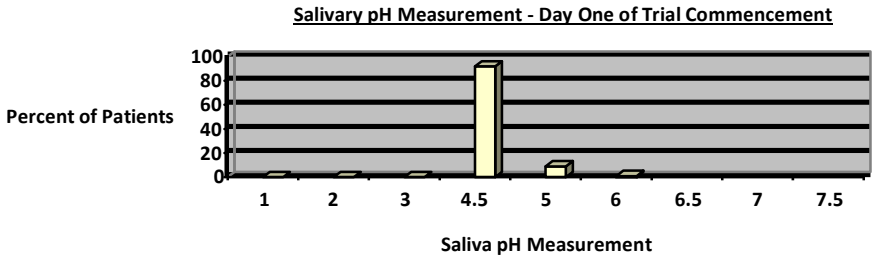
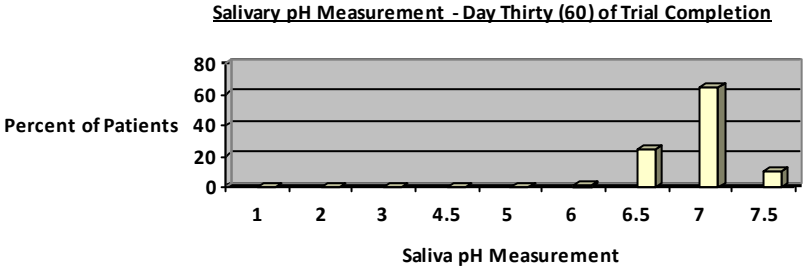


Table: 2



The Table: 3 Graph clearly illustrates the pain reduction level on Hydrolyzed Egg Membrane. In the Single-Arm Pilot Trial the percentage of the study participants experienced greater flexibility and superior free movement. Participants also had a better range of motion for unstable and painful areas of their bodies. Another area of clinical importance was that more than 70% of the trial participants experienced an exemplary improvement in their pain and flexibility at 14 days into the trial.

Table: 3

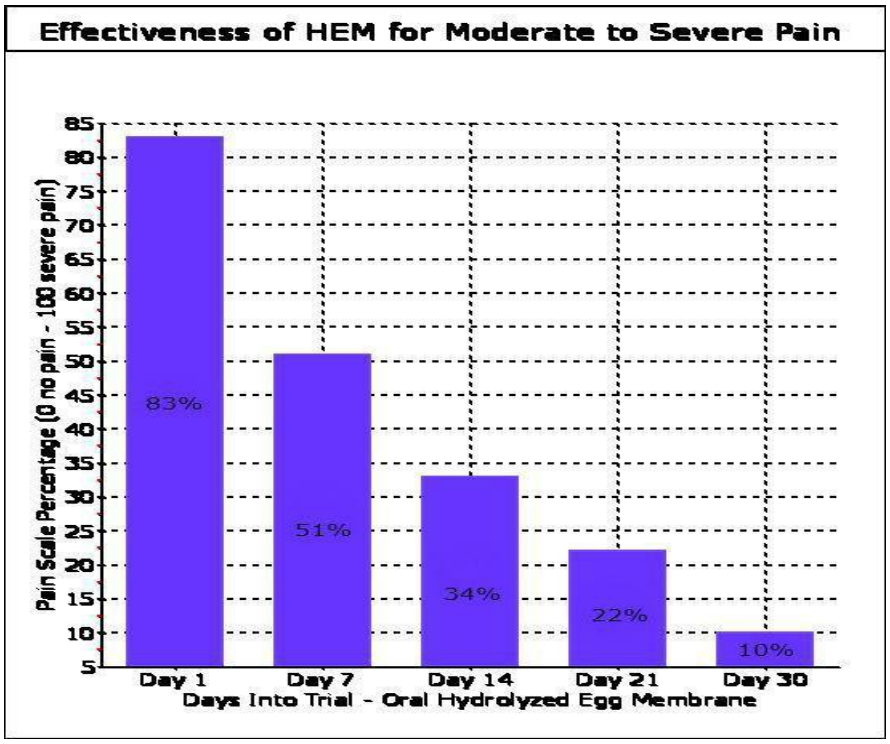
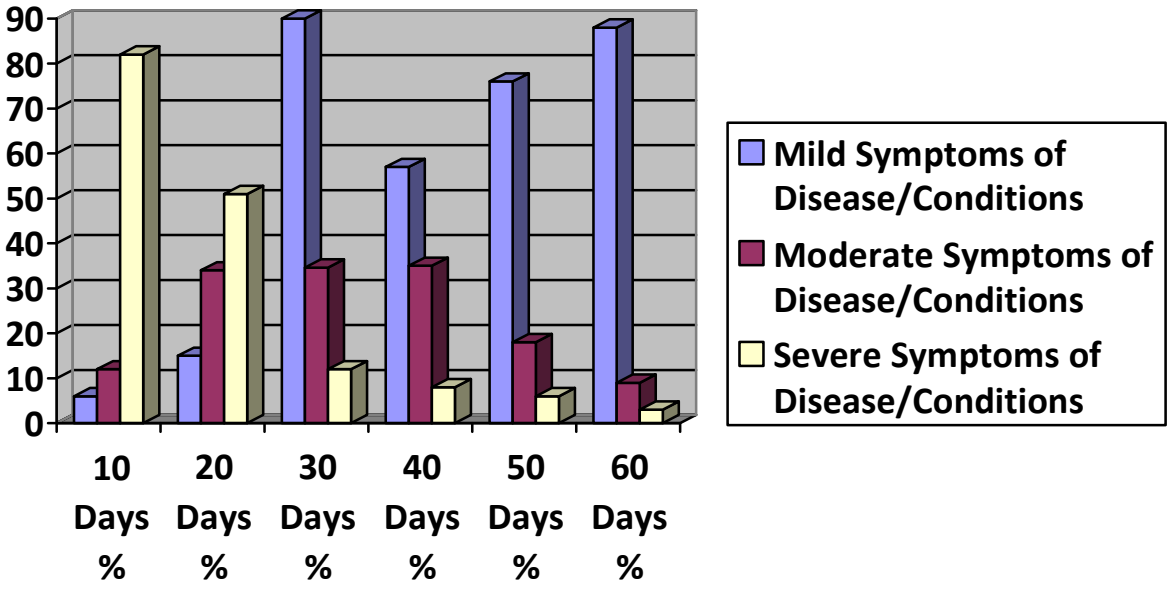


Table: 4 takes a snapshot of general symptoms of targeted diseases and conditions of participants at the start of the trial followed every 10 days until 60 days - at end of trial. The graph clearly shows a significant drop in severe and moderate symptoms that atypically accompanied our target trial audience from start to finish. As we see, the percentile of participants for mild/tolerable symptoms at the start of the trial was very low (low activity threshold, pain, mobility inflammation, etc). At the conclusion of the trial the percentage of participants exhibiting mild and quite tolerable symptoms increased by over 85%, allowing participants to have a better quality of life all round.

Table: 4



Targeted Clinical Response Results:

Supplementation with Hydrolyzed Egg Membrane produced a significant treatment response at seven days for flexibility (74.5% increase; P = 0.035) and at 60 days for general pain (91.7% reduction; P = 0.006), flexibility (70.6% increase; P = 0.006) and range of motion associated pain (77.3% reduction; P = 0.020). There were no adverse events reported during the study and the treatment was reported to be well tolerated by study participants.

Conclusion:

The reporting of results from this human clinical trial demonstrates that Hydrolyzed Egg Membrane is a practical treatment option for the overall management of Joint and Connective Tissue Disease, Symptoms and related superfluous side effects. The study in particular noted an excellent response for participants suffering from Osteoarthritis. A clinical trial dosage of 500 mg taken once per day had a rapid response effect within a 7 day period and over 70% at day 14. The participants' clinical picture continued upward to 60 days into the trial receiving the full weight of the substances capabilities to reduce pain, inflammation and swelling to regional swelling to some degree. The participant's quality of life had increased upwards of 80% after the conclusion of the trial. We found it very intriguing that the blood glucose levels of the 2 new participants started to normalize after half way into the trial. This is an exciting discovery and clearly needs a further look to establish how great the margin of treatability actually is. Hydrolyzed egg membrane should clearly be a viable option for the treatment/management of Joint and Connective Tissue Disease/Disorders, marked pain syndrome with a substantial reduction of symptoms. We can state that our participants and clinical team exhibited or observed no side effects or allergens (as screened prior) throughout the trial of 60 days indicating not only efficacy but safety as well.

Laboratory Analysis and Tested Specifications:

Food for Human Consumption

Typical Analysis:

Chemical:

Purity: 100%
pH: 7.4
Solubility: 100% cold water
Loss on Drying: 2.7
Residue on Ignition: 0.1%
N Assay: 14.4%
L. Assay: 0.2%

Microbiological:

Salmonella, E. Coli Other Pathogenic Germs: Not Detected / No Positive Recovery – ND/g
Total Plate Count Max: 5000 cfu/g
Yeast and Mould: <10 cfu/g

Odor: Neutral

Storage: Cool, dry place away from heat with lid closed tightly upon opening

Signed,

S. G.

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