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Soon they became customers, and **cetyl myristoleate** appeared on the market as a dietary supplement in 1991. **Clinical** trials. There have been four **clinical** ...
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CETYLMYRISTOLEATE RESEARCH
also know as cis-9-cetylmyristoleate, CMO
and cetyl myristoleate

The Effect of cis-9-Cetyl Myristoleate CMO and adjunctive therapy on the course of arthritic episodes in patients with various auto-immune diseases characterized by the common terminology "arthritis" and "psoriasis".

A randomised clinical trial by Dr. H. Siemandi, MD, et al.
Townserd Letter for Doctor's and Patients
August-September, 1997; #169, pp. 58-63

The following are selected extracts.

CONCLUSION: Cis-9-cetyl myristoleate treatment and cis-9-cetyl myristoleate plus GH, SC & HC (referring to nutritional supplements glucosamine hydrochloride (GH), sea cucumber (SC) and hydrolyzed cartilage (HC)) were demonstrated to offer significant benefits over the placebo in the prevention of arthritic episodes. It was further determined that these results could not be obtained with other standard arthritic therapies based upon exhaustive reviews of patient records prior to opening of the study. Cis-9-cetyl myristoleate and cis-9-cetyl myristoleate plus GH, SC & HC treatment also seems to permit some relief to autoimmune inflammatory diseases which may prove to be long-term. This finding could provide additional evidence for the theory, reflected by the earlier anecdotal evidence as well as some animal studies, that cis-9-cetyl myristoleate and cis-9-cetyl myristoleate plus GS, SC & HC may prove to be of major benefit in the future treatment of autoimmune diseases.

Study Objective: Recent published reports offer anecdotal evidence (publication speak for "actual experience of users") that cis-9-cetyl myristoleate may provide significant amelioration of various arthritic conditions. We set out to perform controlled studies to determine if this material was efficacious, either in the short term, or in some measurable manner, over a much longer period.

Methods: A prospective, randomised study design was used to allocate patients to receive cis-9-cetyl myristoleate, cis-9-cetyl myristoleate plus glucosamine hydrochloride (GH), sea cucumber (SC) and hydrolyzed cartilage (HC) and a placebo.

Study design: The study was a 32 week (8 week cycle, 4 in-hospital & 4 in follow-up), multicenter, double-blind, randomised, placebo-controlled parallel trial that compared the efficacy of cis-9-cetyl myristoleate alone, and cis-9-cetyl myristoleate plus GS, SC & HC, administered over a period of 30 days, with placebo, for the treatment of various forms of autoimmune diseases commonly characterised as arthritis and psoriasis. Out of a dose of 90 grams of total fatty acid esters, 18 grams constituted cis-9-cetyl myristoleate. Those study patients who received the support nutrients GS, SC, & HC were given a total dosage of 18 grams each of these nutrients.

The study was conducted under the auspices of the Joint European Hospital Studies Program. This study was designed by a committee, which consisted of rheumatologists and biostatisticians experienced in the development and execution of clinical trials. Oversight of the study was accomplished by an executive committee, composed of the primary researcher and primary statistician, selected participating investigators, consultants; and an independent sight committee consisting of two experienced federally controlled, state health department rheumatologists and one state health department biostatistician.

Results Summary: At the start of this study, the duration, severity, and pattern of arthritic episodes were found to be similar in the 3 treatment groups. At the end of the study it was found that the number of arthritic episodes was significantly reduced, and the duration of episode-free time was significantly prolonged, in the two cis-9-cetyl myristoleate groups compared with the placebo group.

At the end of eight weeks, the response rates were 63.3% with the cis-9-cetyl myristoleate group and 87.3% in the cis-9-cetyl myristoleate plus GS, SC & HC group and only 14.5% in the placebo group.

Joint swelling scores improved in 47.2% in patients using cis-9-cetyl myristoleate alone and 77.2% in patients using cis-9-cetyl myristoleate plus GS, SC & HC. Patients experiencing worsening or no reaction totalled 1.0% in all groups, compared with improvement of 21.1% in placebo group.

DETAILS

Patient population: Four hundred thirty-one patients entered the study. Of these, 106 were randomised to receive cis-9-cetyl myristoleate, 84 were randomised to receive cis-9-cetyl myristoleate plus GS, SC & HC; 226 received a placebo. Fifteen psoriatics received cis-9-cetyl myristoleate plus GS, SC & HC, plus CM-25% concentration topical at a 3X quantity ratio. Even though the study was sponsored by the owners of the respective private hospitals, recruitment was not limited to the typical fee-paying patients. Approximately 27% of the patients were actively recruited in the respective local area. Despite a prolonged accrual period and careful screening, the loss of approximately 11% of the starting participants occurred largely because of the inability to stop the use of tobacco and/or caffeinated beverages

OUTCOME - how "response" was graded

Clinical assessment: Outcome measures of disease activity and therapeutic efficacy were obtained at the time of screening (not more than four weeks before study entry), randomization at week zero, and thereafter at weeks 1, 2, 3, and 4. Outcome measures included a variety of patient-reported, clinical, laboratory and radiographic assessments. Patient self-assessment measures included morning stiffness, night pain, patient overall assessment and Mobility Functional Index as determined by this published procedure. Clinical assessment measures included joint counts, dactylitis, Enthesopathy Index, Spondylitis Articular Index, chest expansion, modified Schober's test, and finger-to-floor test as detailed elsewhere in this paper. Additionally, the presence of symptomatic keratoderma, phalangeal and digital deformation as measured from a normal range of vertical protrusion at rest were measured. These tests, singularly and collectively were then compiled into a patient-by-patient qualitative scale as; none = 0, mild = 1, moderate = 2, severe = 3 and very severe = 4.

Laboratory assessment: Laboratory evaluation included a urinalysis and complete blood cell count, with leukocyte differential and reticulocyte count. Chemical surveys and a Westergren erythrocyte sedimentation rate (ESR) determination were done at every visit by secondary researchers daily in the two hospital settings. The C-reactive protein (CRP) level was evaluated at the first and last day of the hospital stay. At the screening times, blood was drawn for HLA-B27 typing and RF and ANA determinations.

Radiology assessment: At the screening visit, all patients had the following radiographs performed: anteroposterior views of the pelvis and oblique views of the sacroiliac joints. Adverse drug reactions (ADR's). Patients were screened for ADR's at every secondary researcher's visit. Patients were withdrawn from the study medication if any of the following were found; WBC less than 3000/mm³, absolute polymorphonuclear count less than 100000/mm³, acute or progressive decrease in hemoglobin or hematocrit, proteinuria less than 500 mg. for 24 hours, drug fever or significant rash. Biostatistical considerations. Each patient was classified as a treatment responder or nonresponder based on the following definition. Assessment measures were selected a priori, and criteria for clinical improvement and worsening were defined for each patient self-assessment and physician assessment (improvement category); joint pain/tenderness score and joint swelling score (improvement = decrease by 30%; worsening = increase by 30%). Treatment response was then defined as improvement in at least 2 of these 4 measures, one of which must be joint pain/tenderness or swelling, and ITO worsening any of the 4 measures. The study was designated with a 90% power for detecting a placebo response rate of 30% compared with a cis-9-cetyl

myristoleate and cis-9-cetyl myristoleate plus GS, SC & HC response rate of 50%, assuming a 10% withdrawal rate. This resulted in a target sample size of 431 patients with an actual sample size of 382.

In short, the analytical method was the change in primary and secondary outcome measures from baselines to the last available follow-ups analyzed using t-tests for continuous data and chi-square tests for ordinal and categorical data. Mixed-model analyses were done to characterize the response patterns over time using SAS PROC MIXED for continuous data and a program named MIXOR for categorical and ordinal data. All other analyses were conducted using SAS version 6.08. All statistical tests were two-sided and P0.05 was the criterion for statistical significance.

AUTHOR'S DISCUSSION POINTS

The results of this trial suggest that cetyl myristoleate and cetyl myristoleate supporting formulas may be beneficial in the treatment of many forms of arthritic based diseases, including: psoriatic arthritis. The definition of response was determined *a priori* and included assessment of joint pain / tenderness and swelling as well as patient and physician overall assessments. Cetyl myristoleate and supporting formulas produced the best treatment response by a factor of 72.8% more patients than did placebo. Considering the components of response individually cetyl myristoleate and supporting formulas resulted in 70.3% more patients having improved as assessed by physician, and 56.1% more having improved joint swelling. Therefore, while the amount of treatment response using cetyl myristoleate and cetyl myristoleate and supporting formulas seems to be consistent with the treatment affects on joint counts, it is obvious that there is a statistically significant improvement in the use of the CM with supporting formulas. The time-line based response rate of cetyl myristoleate and cetyl myristoleate supporting formulas, not adequately reflected in data, by patient, showed the majority of patients responding to cetyl myristoleate and cetyl myristoleate supporting formulas did so within the first three weeks. Also, not reflected in the data, was the continued use of cetyl myristoleate and cetyl myristoleate supporting formulas beyond the study time limits and dispensed on request to 21 patients. These 21 patients were determined to have received only marginal benefits from cetyl myristoleate and cetyl myristoleate supporting formulas but one more course of treatment showed responses approximately equal to the first patient response results.

Cetyl myristoleate and cetyl myristoleate supporting formulas were well tolerated in this trial. This finding was not unexpected as cetyl myristoleate and the cetylmyristoleate supporting formula components are naturally occurring and have been used as diet supplementation for many years and are widely available singly and in various combinations. In summary, cetyl myristoleate and cetyl myristoleate supporting formulas appear to be beneficial in the treatment of a wide range of arthritic conditions including long standing and refractive cases.

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STUDY 2

A Study on Dose Effectiveness and Patient Response Conducted by the San Diego Clinic

The Purpose: The effectiveness and nontoxicity of CMO (cerasomal-cis-9-cetylmyristoleate) for arthritis symptoms of pain, inflammation, and impaired mobility having been previously established, the purpose of the present study was:

1. To determine optimum dosage levels for various types of arthritis,
2. To determine if different dosage levels would be required relative to the severity of each type of arthritis,
3. To observe response time required for initial and partial relief of symptoms,
4. To observe response time required for complete relief of symptoms, and

5. To determine factors influencing subjects who may not respond to the protocol.

The Subjects: Subjects were volunteers treated as outpatients. They presented with osteoarthritis, rheumatoid arthritis, and other forms of reactive arthritis.

The Study: The study involved 48 subjects. Female subjects (28) ranged from 33 to 82 years of age. Male subjects (20) ranged from 29 to 74 years of age. All races and many ethnic backgrounds were represented. Age, gender, race, and ethnological background appeared to be irrelevant to patient response in this study.

The Protocol: CMO was administered orally in the form of 75mg capsules each morning and evening. The number of capsules and duration of treatment varied for each group of subjects. Subjects were advised to take capsules on an empty stomach with water only; and to avoid tea, chocolate, alcohol, coffee, cola, and other caffeinated drinks for five hours after taking the capsules. Subjects were advised to completely avoid chocolate and alcohol during the entire trial period of two to four weeks duration. With a few exceptions for subjects who could not function without them, steroids were also prohibited. Otherwise diet was not controlled in any way. Subjects were permitted to continue taking their customary pain and non-steroidal anti-inflammatory medications until they were no longer needed. Subjects were asked to visit or call in to report progress at least twice weekly.

The Results: Only two subjects failed to show marked or complete relief of all symptoms of pain and limited mobility normally associated with arthritis. Both of these non-responding subjects had suffered prior hepatic problems: one from alcohol abuse resulting in cirrhosis of the liver; the other, a former professional athlete, presented with considerable liver damage from steroid abuse. Further studies are necessary to determine the role of liver function capacity with respect to this protocol. Liver damage resulting from steroids previously prescribed for arthritis may also prove to be a factor affecting patient response.

Two other subjects showed less than a 75% return of articular mobility. The balance of all subjects reported 80% to 100% return of articular mobility as well as a 70% to 100% decrease of pain. Relief of inflammation frequently resulted in at least partial correction of some deformities. Informal independent trials at clinics, by individual medical doctors, and other health practitioners appear to have brought approximately the same results.

GROUP # 1: Mild to moderately severe osteo-arthritis & reactive psoriatic arthritis

In Group #1, eleven subjects presenting with mild to moderately severe osteo-arthritis and one with reactive psoriatic arthritis were supplied with 16 capsules, two 75mg capsules to be taken each morning and evening for four days. Nine reported about 20% to 30% improvement in articulation and inflammation and about 40% to 50% relief of arthritic pain within 36 hours. In these nine subjects improvement continued rapidly for the next 60 hours, reaching a 70% to 80% overall improvement by the end of the four days. Two of the three latter subjects continued to improve over the following week despite the fact that they were no longer taking the capsules. However, about half of this group experienced the return of some mild arthritic symptoms after about three to five weeks. (Although not included as part of this study, all of the subjects in this group were treated again and their symptoms have not returned.) The patient with reactive psoriatic arthritis also experienced an almost complete reversal of his associated very severe psoriatic skin condition affecting about 20% of his total skin area.

GROUP # 2: Severe to crippling rheumatoid arthritis

In Group #2, nine subjects presenting with severe to crippling rheumatoid arthritis were supplied with 50 capsules to be taken in two series, two 75mg capsules each morning and evening for seven days, with a seven day interval before repeating the same dosage for 5-1/2 more days. Four of these subjects were unable to walk and were accustomed to being transported by

wheelchairs. One, her femur being fused at the hip, was unable to achieve a sitting position for wheelchair transport. She could, however, move about slowly on crutches as long as she was accompanied by someone to aid her in maintaining her balance. Otherwise she could only stand or lie down. The remaining four could move about with canes or walkers. All nine subjects presented with pain, inflammation, and marked deformation of nearly all proximal interphalangeal and large joints. Five presented with limited lumbar flexion and pain in the vertebral column. All had difficulty grasping and manipulating common objects.

Within three days of treatment six subjects in the group reported a 30% to 50% decrease in pain and 20% to 30% increase in joint mobility, and three subjects reported little change. Within seven days five subjects reported a 70% to 90% decrease in pain and 70% to 80% increase in joint mobility. Three subjects reported to be totally free of pain with almost complete return of joint mobility and marked improvement in joint deformation. One patient reported no perceptible change.

On the fourteenth day, at the end of the one week interval without treatment, six subjects reported minor continuing improvement; two reported maintaining their improved status, and one continued to show no improvement. Treatment was resumed on the fifteenth day for 5-1/2 more days.

By the end of the treatment period all but two subjects reported to be 90% free of pain with return of 70% to 100% mobility. The fused hip joint remained fused, of course, but with a return of over 70% mobility in other joints the subject felt hip surgery now to be worth consideration. The one non-responsive subject proved to have cirrhosis of the liver, which may have been the reason for her inability to respond to treatment.. Further investigation is necessary to determine the role of liver function in this protocol.

GROUP # 3: Mild to moderately severe rheumatoid arthritis

In Group #3, fourteen subjects presenting with mild to moderately severe rheumatoid arthritis were supplied with 24 capsules, two 75mg capsules to be taken each morning and evening for six days. After three days of treatment eleven reported about 20% to 30% improvement in articulation and inflammation, and about 40% to 50% relief of arthritic pain. In these eleven subjects improvement continued rapidly over the next four days, approaching the 80% to 100% level. The remaining three subjects reported similar improvements by the end of the fourth day, with an overall improvement of 70% to 80% after seven days.

Most of the subjects continued to report minor additional improvement for one week or more even though they were no longer under treatment. However, six in this group began to experience the return of some mild arthritic symptoms after about three to four weeks. (Although not included as part of this study, all of the subjects in this group were treated again and their level of improvement has subsequently stabilised).

GROUP # 4: Severe to crippling osteo-arthritis

In Group #4, fourteen subjects presenting with severe to crippling osteo-arthritis were supplied with 50 capsules to be taken in two series, two 75mg capsules each morning and evening for seven days, with a seven day interval before repeating the same dosage for 5-1/2 more days. Three of these subjects were unable to walk and were accustomed to being transported by wheelchairs. The other eleven could move about with crutches, walkers, or canes. All presented with pain, inflammation, and marked deformation of nearly all interphalangeal and large joints. Four presented with limited lumbar flexion and pain in the vertebral column. Ten had difficulty grasping and manipulating common objects.

After four days of treatment ten in this group reported 30% to 50% improvement in articulation and inflammation and about 40% to 60% relief of arthritic pain. In these ten subjects

improvement continued rapidly over the next three days, reaching 80% to 100% by the end of seven days. One reported no perceptible change.

On the fourteenth day, at the end of the one-week interval without treatment, nine subjects reported continuing minor improvement, four reported maintaining their improved status, and one continued to show no improvement. Treatment was resumed on the fifteenth day for 5-1/2 more days.

By the end of the treatment period eleven subjects reported 80% to 100% relief of pain with a return of 80% to 100% mobility. Two subjects reported 70% to 80% return of articular mobility with a 70% to 90% reduction of arthritic pain. The one non-responsive subject proved to have previous liver damage as a result of sports-related steroid abuse. Further studies are necessary to determine the role of liver function in this protocol.

SUMMARY

The results of this study lead to several conclusions regarding its five principal objectives:

1. Optimum dosage levels appear to be equal for all three types of arthritis investigated: osteo-arthritis, rheumatoid arthritis, and reactive psoriatic arthritis. This is evidenced by the gradual return of minor arthritis symptoms in several of those treated with only 16 or 24 capsules, and no regression in those treated with 50 capsules in two series separated by one week without treatment.
2. Dosage level requirements appear to be equal irrespective of the severity of the subject's condition.
3. Initial response time for minor improvement appears to vary from two to seven days irrespective of the severity of the subject's condition.
4. The time for maximum attainable response appears to vary from seven to twenty-one days, resulting in 70% to 100% overall improvement. (Apart from this study, three of the most severely afflicted subjects were treated again after a five-week interval, resulting in an additional 10% to 20% overall improvement.)
5. The two non-responding subjects both proved to have suffered previous damage to the liver from steroid or alcohol abuse, indicating that impaired liver function may preclude success with this protocol.

In addition, it was evident that for many subjects the relief of inflammation resulted in marked improvement in joint deformation.

(This study was conducted at several different sites after the model prepared by the San Diego Clinic.)

CASE HISTORIES

Here are some condensed case highlights from The San Diego Clinic Trials

From case history #38: Medical Doctor. Pain and stiffness in hands for several years. Unable to perform simple office surgery. One day of CMO brought relief. Dexterity and fine surgical ability returned gradually. Ordered CMO for his patients.

From case history #39: Male. Medical Doctor/psychiatrist. This physician complained of persistent pains along his spine and in his feet. He became completely free of pain in both the spine and feet within two days of starting CMO capsules. Remission continues.

From case history # 33: Medical Doctor. Auto wreck ten years earlier damaged hip, caused limp and arthritis. CMO relieved pain permanently in one day for the first time after many years. The limp problem is irreparable. Ordered CMO for his patients.

From case history # 06: Female. Age 45. Arthritis attack worsened rapidly over a period of only seven months. Required a wheelchair to be moved about. Frequently unable to leave bed in mornings because of debilitating pain. Seeking relief, she worked with a personal trainer. She was incapable of holding a five pound weight, unable to make a fist. Saw immediate improvement with CMO in just three days. Two weeks after the first, she took a second course of CMO. She is now able to perform a full workout, has no difficulty making a fist, wakes in the mornings free of pain, and has resumed a normal active life.

From case history # 29: Female. Age 63. Despite devoted adherence to a truly natural diet, suffered severe osteo-arthritis in most joints for over ten years. Woke to agonising pain. Even simple chores were arduous. CMO brought total relief in ten days.

From case history # 24: Female. Age 50. Family history of arthritis. Pain in shoulders. Severe pain, limited mobility, and gross swelling in hands and fingers. By the third day of CMO, hands were free of pain, mobility had increased immensely, and finger swelling decreased so dramatically she had to have all her rings re-sized. Repeated treatment three weeks later. Totally free of pain and inflammation since. For the first time in many years, she was recently delighted to experience a pain-free skiing holiday.

From case history # 22: Female. Clinically obese. Arthritis in neck and spinal column resulting in joint mobility limitations. Despite impaired liver function which frequently inhibits the benefits of CMO, her range of motion increased by 100% within one week. A repeat course of CMO two weeks later has resulted in even greater and continuing improvement.

From case history # 03: Male. Age 32. Rheumatoid arthritis at age 25. Family history of arthritis. Seven years of pain in hands, shoulders, legs, and ankles. Although subject saw substantial improvement after taking CMO for three days, he did not experience complete relief with continuing remission for about two weeks. He has subsequently enjoyed skiing holidays and has been able to return to playing golf without the discomfort of any pain

From case history # 17: Female. Age 60. Physician. Relentless pain from hip injury one year prior. Diverse treatments and medicines brought little relief. With CMO and massages to reduce edema and improve muscle activity, her pain gradually diminished in two weeks. Now remains completely free of pain.

From case history # 15: Lifelong athlete. Arthritic pain and/or stiffness in hands, feet, knees, neck, and shoulders _ especially with exposure to the cold. With three days of CMO, was totally free of pain with dramatically increased articulation in the joints. Further improved mobility came with a repeat set of CMO three weeks later. He now enjoys skiing and other activities with the vigour and delight he lost so many years ago.

From case history # 11: Male. Age 58. Ex football player. Clinically obese. Had knee surgery three times about 15 years ago. Had extreme pain upon lying down. Often slept in a recliner chair instead. With his first evening dose of CMO capsules, he slept soundly and arose the next morning completely free of pain. He has enjoyed continuing pain-free remission ever since the first day.

From case history # 08: Male. Medical Doctor/psychiatrist. Pains in feet daily for over five years. With CMO almost constant pain disappeared within a day. Ordered CMO for his patients.

From case history #32: Female. Age 66. Rheumatoid arthritis rendered hands useless, gnarled, inflexible, agonisingly painful six years ago. Pain relieved and full use of hands restored after five days of CMO.