CMO_{TM} (Cerasomal-cis-9-cetylmyristoleate) Study on Dose Effectiveness and Patient Response

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The effectiveness and nontoxicity of CMO_{TM} (cerasomal-cis-9-cetylmyristoleate) for arthritis symptoms of pain, inflammation, and impaired mobility having been previous 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 or 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.

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

This 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.

CMO_{TM} was administered orally in the form of 75 mg 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 with water only on an empty stomach; 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 not-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.

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 form 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.

MILD TO MODERATELY SEVERE OSTEOARTHRITIS & REACTIVE PSORIATIC ARTHRITIS

In Group #1, eleven subjects presenting with mild to moderately severe osteoarthritis and one presenting with reactive psoriatic arthritis were supplied with 16 capsules, two 75mg capsules to be taken each morning and each 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.

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 to be taken each morning and each 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 this 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 in other joints, the subject felt hip surgery 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.

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 presenting with severe to crippling osteoarthritis were supplied with 50 capsules to be taken in two series, two 75 mg capsules to be taken each morning and each 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 of the subjects in this group reported a 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 subject 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 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 four principal objectives.

1.) Optimum dosage levels appear to be equal for all three types of arthritis investigated: osteoarthritis, 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 to 24 capsules, and no regression in those treated with 50 capsules in two series separated by a one week period 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% improvement in their conditions.)

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.

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This study was conducted at several different sites following a model prepared by the San Diego Clinic.