



CLINICAL SUMMARY REPORT

INTRODUCTION

ARTHRI-ZEN RELIEF is a mixture of extracts of Juniper, Goldenrod, Dandelion, Meadowsweet and Willow. These herbs have long been used in folk medicine to treat a wide variety of medical conditions, including arthritic pain, stiffness and swelling. The major pharmacologically active ingredients of these herbs include terpenes, flavonoids, salicylates and complex glycosides, among others. The relief of pain and inflammation is via blockade of the production and release of certain prostaglandins and cytokines. They also act by blocking the production and/or metabolism of certain neurotransmitters and by effecting excess water removal. The mechanisms of action are similar to those of commonly prescribed anti-arthritic drugs, without side effects known to the prescription products.

OBJECTIVES

The primary objective is to establish the effectiveness of ARTHRI-ZEN against placebo for relief of mild to moderate arthritis pain and arthritis-related symptoms. The secondary objective is to assess the safety and tolerability of ARTHRI-ZEN.

STUDY MEDICATION

ARTHRI-ZEN RELIEF is made from a mixture of extracts of Juniper, Goldenrod, Dandelion, Meadowsweet and Willow. The mixture is combined with whole grape extract and spray-dried according to the Manufacturer's proprietary method. The resulting powder is encapsulated in cellulosic vegetarian capsules. The placebo capsules are prepared in the same manner and are identical in appearance to the active capsules.

METHODS

Ethical Considerations

The study protocol was reviewed by Research IRB, Inc and approved on August 15, 2005. All subjects signed an Informed Consent after having been fully informed of the nature and method of the study. The study was conducted in accordance with the guidelines of the World Medical Assembly, GCP guidelines of ICH E6, and the FDA guidelines for the protection of human subjects.



Patient Selection

Thirty (30) patients with mild to moderate arthritis pain as determined by the investigator, and who met the inclusion/exclusion criteria were included in the study. The patient demographics are presented in Table I.

Study Design

The study was placebo-controlled, double-blinded and randomized. Eligible patients were divided into two parallel groups and randomly assigned at a 1:1 ratio to receive ARTHRI-ZEN RELIEF or placebo. The treatment was for a four week period in patients with mild to moderate arthritic pain and arthritis-related symptoms.

Efficacy and Safety Evaluation

Clinic Evaluation-at the baseline visit and Day 30 visit, patients were rated for symptomatic severity (none, mild, moderate) with regards to inflammation, swelling and crepitus.

Self-assessments-completed at baseline, Day 7, Day 20 and day 30 by patients at home and verbally reported during the scheduled phone contact. The assessments include overall pain, overall arthritis effects on daily living, and overall level of stiffness. An analogue scale of 0 to 10 was used for self-assessment, with 10 having the maximum degree of arthritic effects and 0 having no effect.

Safety Assessment-at each interview/visit, patients were asked open questions as to their medical problems or new medications since last evaluation. Any adverse event/experience reported by the patients was recorded and the relationship to study medication evaluated.

PROCEDURES

Dosing

Each patient received an initial physical exam and history including assessment of inflammation, swelling and crepitus. Qualified patients were dispensed the study medications for self-administration at home. From Day 1 through Day 7, patients were instructed to take two capsules in the morning and two capsules in the evening (4 capsules daily). Patients were instructed to keep the doses at 12 hours apart, if possible. From Day 8 through Day 30, patients were instructed to take two capsules in the morning, each morning (2 capsules daily). All doses were taken approximately 10-15 minutes before a meal.



Clinical Evaluation

Patients were evaluated on Day 1 (baseline) and Day 30 for inflammation, swelling and crepitus. Self-assessments were completed on Day 1 (baseline), day 7, Day 20 and Day 30 (end of study), including overall pain, overall arthritis effects on daily living and overall level of stiffness. Adverse event/experience was recorded via phone interview, throughout the study period.

Data Analysis Plan

Comparison between the active treatment group and the placebo group was made by descriptive statistics and frequency analysis, using SPSS, 12.0. The scores for overall pain ("pain"), overall effects on daily living ("living") and overall level of stiffness ("stiffness") were depicted as absolute values to indicate the improvement (if any) of these clinical conditions. The scores were also expressed as a percent of the baseline value to indicate the degree of improvement on a relative basis.

Frequency analysis derived the percent of patient population in each of the three categories for symptomatic severity, "none", "mild", and "moderate" for inflammation, swelling and crepitus. The comparison was made between baseline (Day 1) and the end of study (Day 30). The level of relief is defined as a percent reduction in the "mild", or "moderate" category and a percent increase in the "none" category.

Alternatively, the level of relief was expressed as a percent reduction of pain, living and stiffness scores between the baseline (Day 1) and the end of study (Day 30). Subjects with at least 20% reduction in score (relief), with no change of score (no relief) and with increase of score (worsening) were tabulated.

Adverse events, if any were listed and relationship to study medication evaluated.

RESULTS AND DISCUSSION

Thirty (30) patients completed the study; Subject 17 was withdrawn from the study and was replaced by subject 31. Pain, living and stiffness scores were complete for all subjects except Subject 4, whose Day 30 ratings were missing. The inflammation, swelling and crepitus evaluations were complete on all subjects except Subject 4 due to early termination. The pain, living and stiffness scores at baseline, Day 7, Day 20 and Day 30 for all subjects were listed in Table II. The inflammation, swelling and crepitus evaluations were listed in Table III.



Upon review of baseline data for Subjects 6 and 7, it was found that both subjects had low baseline scores and no clinical symptoms to warrant their inclusion in the study. Further, Patient 14 of the active group was found to have an abrupt surge of pain score on Day 30, which was not reflected in the corresponding symptomatic rating on the same day. It was felt that Subjects 6 and 7 were admitted by error, and Subject 14 may not have consistently reported the results. A decision was made to exclude these three subjects from the final data analysis. Therefore, the following analysis is based on twenty seven (27) subjects, 14 from the placebo group and 13 from the active group.

Figure 1 shows the scores for pain, living and stiffness in the placebo group. Interestingly, a small magnitude of placebo effect did not surface until the second week of study, and leveled off at the beginning of the third week. In comparison, Figure 2 shows a clear trend of score reduction for all three measurements over the 30 day period. The pain scores were 4.46 at the baseline, reducing to 3.69 at Day 7, 3.23 at Day 20 and 3.08 at Day 30. The living scores decline in a similar manner, from 4.46 at the baseline to 3.62, 3.31 and 3.25 at Day 7, 20 and 30, respectively. Of the three measurements, the stiffness scores showed the steepest decline, from 4.69 at the baseline to 3.69, 3.08 and 2.92 at Day 7, 20 and 30, respectively.

Alternately, the scores were expressed as a percent of the baseline. As in Figure 1, Figure 3 showed no placebo effect during the first week of drug administration. The placebo effect was about 10% for both the overall daily living and the overall pain, beginning at Day 7 and leveled off from Day 20. The placebo effect for stiffness also began to surface at Day 7 and appeared to level off at slightly over 15% from Day 20. As shown in Figure 4 on a percent basis, the Group 2 pain score was reduced by 17.2, 19.5 and 31% from the baseline at Day 7, 20 and 30, respectively. In a parallel fashion, the living score was reduced by 18.8, 25.7 and 27.1% from the baseline at Day 7, 20 and 30, respectively. The stiffness scores showed the largest percent reduction, 21.3, 34.4 and 37.7% from the baseline at Day 7, 20 and 30, respectively.

Frequency analysis was performed on inflammation, swelling and crepitus for which the ratings were designated as “none” (no symptoms), “mild” (mild symptoms) and “moderate” (moderate symptoms). The results showed that the drug effect on inflammation and crepitus were inconclusive. Only swelling was shown to have an increased frequency on “none” and a reduced frequency on “mild” and “moderate” ratings. Since frequency analysis was inconclusive, we deem it appropriate to focus on the descriptive statistics of pain, living and stiffness.

Table IV shows percent reduction of pain, living and stiffness scores between the baseline (Day 1) and the end of study (Day 30). By the end of the 30-day treatment, 67.6% of study subjects showed a reduction of pain, 75% of the study subjects reported an improvement in daily living, and 58.3% of the subjects



reported a reduction in stiffness. Sixteen point seven (16.7) % of the study subjects reported little or no pain relief, 16.7% of subjects reported little or no improvement in quality of living, and 33.3% of the study subjects reported little or no reduction in stiffness. No adverse event or experience was reported by the study subjects, indicating that ARTHRI-ZEN RELIEF is safe and well tolerated.

In conclusion, ARTHRI-ZEN RELIEF showed a positive effect on overall pain, overall daily living and overall level of stiffness in patients with varying degrees of arthritis.

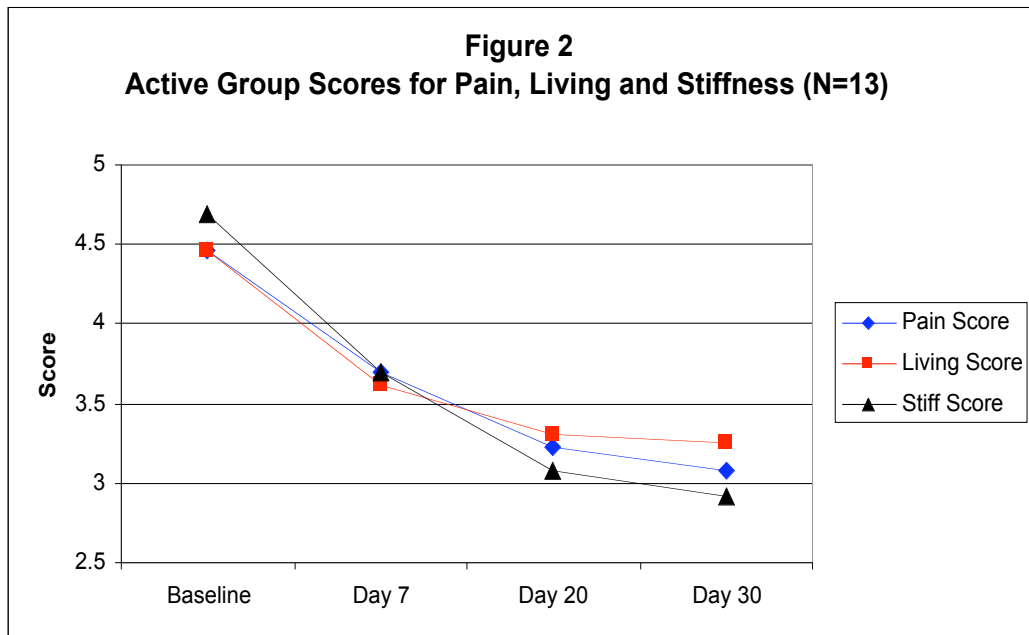
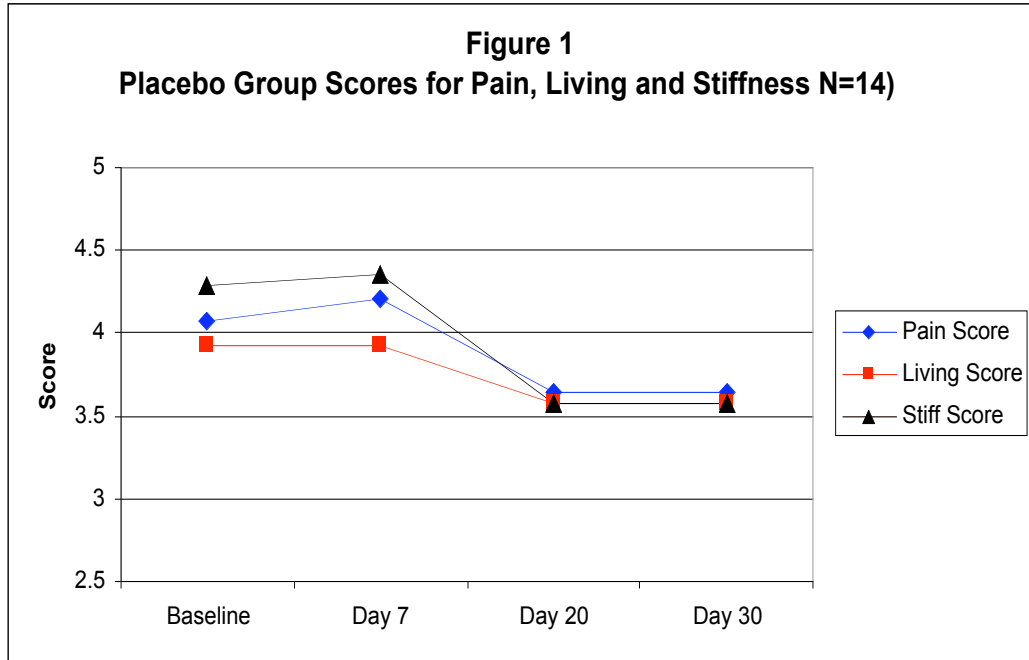
Study subjects were enrolled from August 16, 2005 to October 11, 2005 at our dedicated research center in West Palm Beach, Florida.
This final report has been printed on November 3, 2005.

A handwritten signature in black ink, appearing to read "David Scott", is written over the printed name.

David Scott, MBA, CCRC
President
Palm Beach Research Center



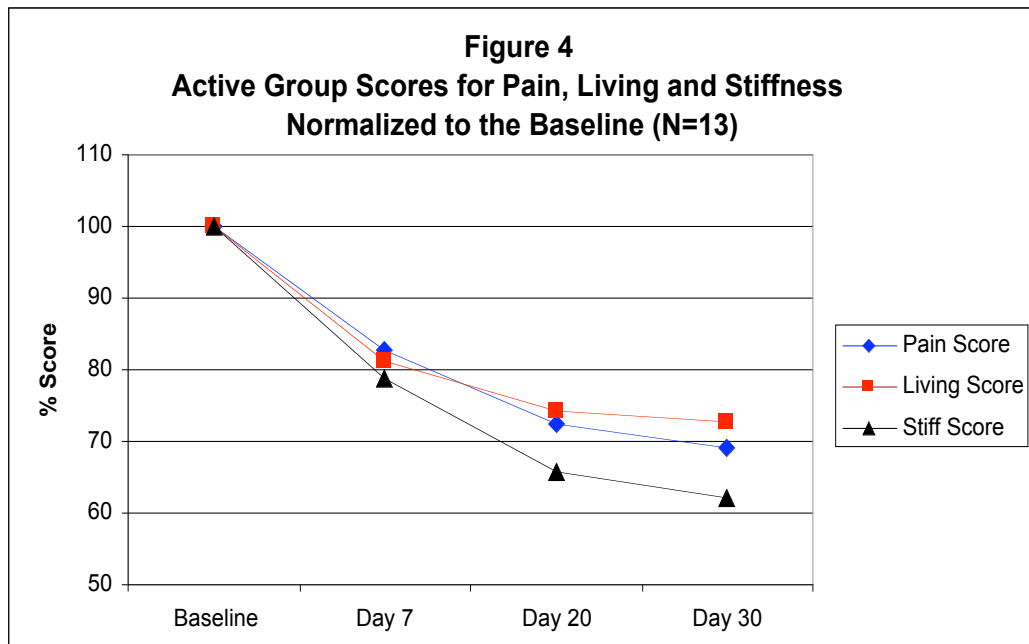
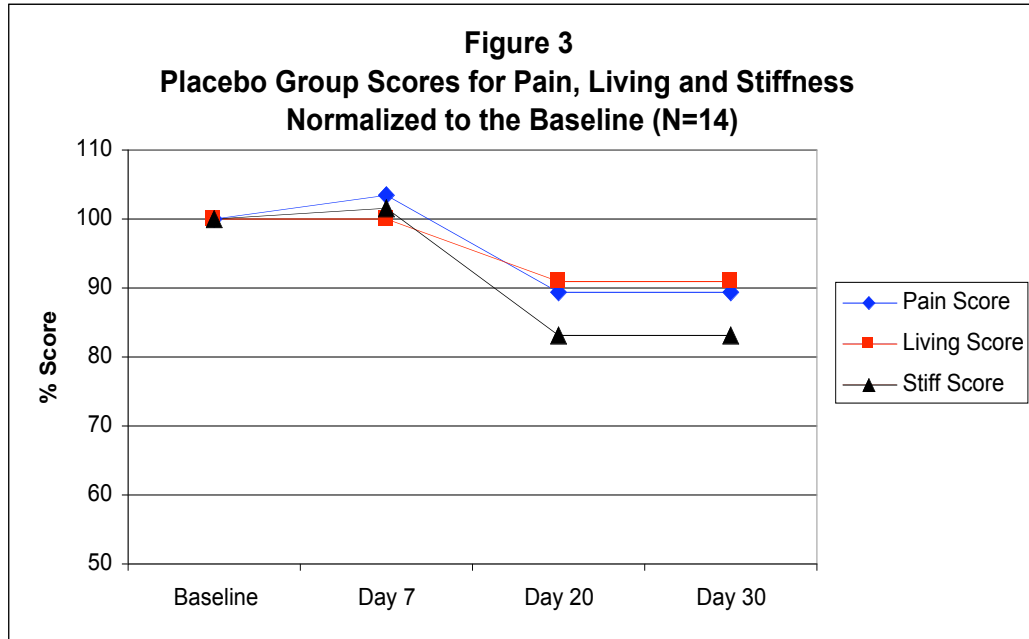
ARTHRI-ZEN RELIEF



Conducted at Palm Beach Research Center

16/AUG/2005 to 11/OCT/2005

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Table I
Patient Demographics

Subject #	Gender	Race	Age (yr)	Weight (lb)	Height (in)
1	M	W	78	215	68
2	F	W	81	113	62
3	F	W	59	168	64.5
4	F	B	59	149.75	62.75
5	F	W	59	232	63.5
6	M	W	63	203.25	72
7	M	W	88	186	72
8	F	W	47	169	64.6
9	F	B	45	304.5	71
10	F	W	65	257.5	67.5
11	F	W	68	210	66
12	M	W	76	188	69
13	M	W	71	183	66.8
14	M	W	79	243	68
15	M	W	75	219.75	66.3
16	F	W	80	167	67
18	F	W	47	212	65
19	F	W	73	121	66
20	M	W	51	266	72
21	F	W	53	135	64
22	M	W	51	161	65
23	F	B	54	234	63
24	F	B	49	267.75	64
25	M	B	44	283	71
26	M	W	34	250	75
27	F	W	59	253.75	65.5
28	M	W	67	191	67
29	F	B	70	204.75	65.25
30	F	W	70	164	65.5
31	F	Bi-Racial	60	140	51

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