

Effects of Arthro-7[®] in relieving symptoms of osteoarthritis with mild to moderate arthralgia

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Background: Osteoarthritis is a common chronic disease affecting aged populations. Conventional therapies tend to result in side effects when used long-term. Arthro-7[®] (Robinson Pharma, Orange County, CA, USA) has been used by osteoarthritis patients for more than 10 years in the USA and has showed promising effects at relieving osteoarthritis-related symptoms. A previous small, double-blind study has shown some positive effects of Arthro-7 in relieving symptoms of osteoarthritis. The current study was performed specifically in osteoarthritis patients with mild to moderate arthralgia.

Methods: A total of 100 subjects over the age of 50 years old who were diagnosed with osteoarthritis and had at least one of the related symptoms were recruited to the study. After primary evaluation, 64 eligible males and females with mild or moderate degrees of arthralgia were randomly assigned 12-week treatment with either Arthro-7 or placebo. The primary outcome measurement was changes in the scores of the related symptoms before and after treatment, using the modified Western Ontario and McMaster Universities Arthritis Index (WOMAC) 3.1 questionnaire. Prior to and at the end of the study, evaluations of symptom scores were recorded. Additionally, self-reported overall changes were recorded at the end of 2, 4, and 8 weeks of treatment and at the end of the study (12 weeks).

Results: Arthro-7 improved most symptoms significantly compared with placebo, as indicated by significant reductions in symptom scores. In the Arthro-7 group, 74.5% of the participants reported symptom improvement over the study period versus only 16.3% in the placebo group.

Conclusion: In this study, Arthro-7 has shown potent effects in improving and relieving osteoarthritis-related symptoms, particularly joint pain, ankylosis, and difficulty going down stairs.

Keywords: joint pain, ankylosis, arthroncus, WOMAC 3.1

Introduction

Osteoarthritis is a common chronic and degenerative osteoarthropathy,¹⁻³ characterized by primary or secondary degeneration of the articular cartilage with hyperplasia of the bone under the cartilage.⁴⁻⁶ The main clinical manifestations are chronic arthralgia, ankylosis, and arthroncus with functional disorder. The disease generally involves the knees, spine, and interphalangeal joints. Arthritis affects nearly 50 million people in the USA,⁷ with prevalence rising as the population ages.⁸

Currently, analgesics and nonsteroidal anti-inflammatory drugs (NSAIDs) are the routine therapies for osteoarthritis. However, prolonged administration of these medications may cause side effects and complications.⁹

Arthro-7[®] (Robinson Pharma, Orange County, CA, USA) is a nutritional supplement that has been marketed in the USA for more than a decade for the potential relief

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of the symptoms of osteoarthritis, especially arthralgia, with no significant adverse effects reported so far. A previous study showed that Arthro-7 noticeably benefits osteoarthritis patients, especially in terms of pain relief.¹⁰ However, that study was undertaken mainly in patients with severe osteoarthritis. The current study, also a randomized, double-blind, controlled study in Chinese population, examined osteoarthritis patients with only mild to moderate arthralgia. In addition, we also tested a different dose regimen, with patients using a high dose for the first 4 weeks, before switching to a maintenance dose for the remaining 8 weeks of the study.

Methods

Materials

The Arthro-7 and placebo capsules were provided by Robinson Pharma (Orange County, CA, USA). The Arthro-7 was in the form of soft gels containing vitamin C, collagen (from chicken) cetyl myristoleate (CMO), lipase, methylsulfonylmethane (MSM), curcumin, and bromelain (Table 1). The main ingredient of the placebo softgel was corn oil. In addition, there were gelatin, glycerin, purified water and titanium dioxide, and artificial food coloring.

Subjects

A total of 100 subjects (51 males and 49 females) over the age of 50 years old who were diagnosed with osteoarthritis¹¹ and had at least one of the related symptoms (arthralgia, ankylosis, arthroncus, a walking problem, difficulty getting up from bed, or difficulty going down stairs) were recruited from the outpatient department of the community health service center of Tangqiao in Shanghai, China, in November 2011. The study excluded patients also suffering from cancer, calculus, a gastric ulcer, or gout, as well as those who had been using anti-inflammatory drugs, bromelain, antibiotics, or antiplatelet agents. All potential participants met the symptomatic diagnostic standards of the American College of Rheumatology, based on physical and X-ray examinations.¹² All potential participants were screened by physical examination for arthralgia. Degree of arthralgia was determined

as being between 0 and 4, as measured using the modified Western Ontario and McMaster Universities Arthritis Index (WOMAC) 3.1, where 0 indicates the absence of arthralgia and 4 indicates severe arthralgia.¹³ The WOMAC Index is a standardized questionnaire widely used by health professionals to evaluate the condition of patients with osteoarthritis.^{14,15} According to our study design, only 64 subjects (31 males and 33 females) with mild or moderate arthralgia – that is, arthralgia with a WOMAC Index score ≤ 2 – were eligible to participate in this study. All participants provided written, informed consent prior to participating.

Intervention

Each of the 64 eligible participants was randomly assigned to the “Arthro-7 group” or the “placebo group” at a ratio of 1:2. Patients in the Arthro-7 group received two capsules of Arthro-7 orally twice per day for the first 4 weeks, followed by two capsules once per day from week 5 to week 12. We were interested in the immediate short-term effect of Arthro-7 at a high dose level, followed by a maintenance dose, thus a dose-change regimen was used at 4 weeks after the initial high dose intervention. Meanwhile, patients in the placebo group received a similar-looking bottle of capsules (the only difference was the color of the bottle cap [the treatment bottle had a white cap and the placebo bottle had a yellow cap, but this was blinded for both study subjects and researchers]) and took these at the same frequency. The total intervention period lasted for 12 weeks. All participants were followed up every 2 weeks in the first month of intervention, and once per month for the following 2 months. Medications were dispensed with follow-ups. All follow-ups for both the Arthro-7 group and placebo group were completed. There were no losses to follow-up until the end of the intervention.

Assessment of outcomes

The objective of the study was to determine whether daily use of Arthro-7 would relieve symptoms of osteoarthritis (arthralgia, ankylosis, arthroncus, any walking problem, difficulty getting up from bed, and difficulty descending stairs) in the designed populations.

At baseline and the end of the intervention period, doctors gave scores for the symptoms mentioned for every participant, determined by physical examination, ranging from 0 to 4, with 0 indicating the absence of a given symptom and 4 indicating a severe degree of the symptom. The age, sex, history of alcohol consumption, and medical and medication history of all participants were also collected at baseline.

Table 1 Major ingredients of Arthro-7®

Vitamin C
Collagen (from chicken)
Cetyl myristoleate
Lipase
Methylsulfonylmethane
Curcumin
Bromelain

Along with follow-up, self-reported side effects and adherences were recorded.

Statistical analysis

Variables were compared between the two groups using Student's *t*-test for interval variables and either the Chi-square or Fisher's exact test for nominal variables. Paired *t*-test was applied to compare the symptom scores before and after the intervention. Simple linear regression was used to estimate the difference of score reduction between the two groups. Stata/MP (v 11.2; Statacorp, College Station, TX, USA) was used for all statistical analyses. The alpha level we chose was 0.05. Analyses were conducted using intent-to-treat analysis. All *P*-values presented are two-sided.

Results

Of the 64 eligible participants who underwent randomization at the ratio of 1:2, 22 were assigned to the Arthro-7 group and 42 to the placebo group, with no losses to follow-up until the end of the study. There was no significant difference in adherence between the two groups.

Baseline data

The baseline characteristics of the two groups were compatible in terms of age, sex, history of alcohol consumption, and whether the participants had "used osteoarthritis drugs recently (including herbs and OTC [over the counter] drugs)."

Baseline symptom scores were also compatible for most osteoarthritis symptoms (arthralgia, ankylosis, arthroncus, difficulty getting up from bed and difficulty descending stairs). The only exception was for walking problems, for which the mean scores were 0.50 and 0.07 for the Arthro-7

and placebo groups, respectively ($P = 0.0012$). Generally, the two arms were well balanced at baseline due to randomization (Table 2).

Results after intervention

After 12 weeks, all six symptoms of study focus were reassessed. Table 3 displays the score for each item and distribution of each symptom in the two groups. The individual score for arthralgia was statistically different between the two arms (Table 3).

Paired *t*-test comparing the symptom scores before and after the intervention showed that, except for difficulty in getting up from bed, all other symptoms were relieved by Arthro-7 treatment. The same kinds of change were not observed in the placebo group (Table 4).

To reveal detailed associations, the individual score reductions, specific to every symptom of interest for each participant, were calculated. Linear regression was conducted to estimate the differences in the symptom-specific score reduction between the two groups. Additional score reductions resulting from Arthro-7 use, compared with placebo; the statistical significance of the differences; and 95% confidence intervals for the estimates are given in Table 5.

Almost all the symptoms (the only exception was difficulty getting up from bed), as shown in Table 5, were significantly relieved as a result of Arthro-7 treatment. For example, we found that the symptom score for arthralgia would decrease 0.911 points more, on average, in the Arthro-7 group than in the placebo group. Other parameters in Table 5 can be interpreted analogously.

The self-reported overall symptom improvement during the study period suggests that Arthro-7 has potent effects. After 2 weeks of intervention, 39.2% of participants

Table 2 Baseline characteristics

Characteristic [‡]	Arthro-7 (n = 22)	Placebo (n = 42)	Total (n = 64)
Sex, n			
Male	9	22	31
Female	13	20	33
Age, y (±SD)	66.21 ± 7.04	66.08 ± 11.15	
History of alcohol consumption, n (%)	4 (18.2)	14 (33.3)	
Used osteoarthritis drugs recently, (%)	12 (54.5)	13 (31.0)	
Arthralgia, mean ± SD	1.77 ± 0.528	1.74 ± 0.445	
Ankylosis, mean ± SD	1.00 ± 0.816	0.69 ± 0.643	
Arthroncus, mean ± SD	0.18 ± 0.395	0.10 ± 0.297	
Walking problem*, mean ± SD	0.50 ± 0.673	0.07 ± 0.342	
Difficulty in getting up from bed, mean ± SD	0.14 ± 0.468	0.07 ± 0.261	
Difficulty descending stairs, mean ± SD	1.00 ± 0.873	0.69 ± 0.680	

Notes: [‡]Symptom scores ranged from 0 to 4, using the modified WOMAC[®] 3.1 questionnaire; *statistically significant difference, $P = 0.0012$ (Student's *t*-test).

Abbreviation: SD, standard deviation.

Table 3 Symptom scores after intervention

Symptom [‡]	Arthro-7 [®] , mean ± SD	Placebo, mean ± SD	t-statistic	P
Arthralgia*	0.91 ± 0.750	1.79 ± 0.717	4.5733	<0.0001
Anchylosis	0.50 ± 0.598	0.74 ± 0.701	1.3555	0.1802
Arthroncus	0.00 ± 0.000	0.10 ± 0.297	1.4978	0.1393
Walking problem	0.23 ± 0.528	0.07 ± 0.342	-1.4288	0.1581
Difficulty in getting up from bed	0.09 ± 0.294	0.07 ± 0.261	-0.2716	0.7868
Difficulty descending stairs	0.45 ± 0.596	0.74 ± 0.885	1.3486	0.1824

Notes: [‡]Symptom scores ranged from 0 to 4, using the modified WOMAC[®] 3.1 questionnaire; *statistically significant difference, $P < 0.05$ (Student's t-test).

Abbreviation: SD, standard deviation.

in the Arthro-7 group reported overall symptom relief, compared with none in the placebo group. At the end of the first month of intervention, 45.1% of participants in the Arthro-7 group reported symptom improvement. Four weeks later, 60.8% of participants in the Arthro-7 group reported symptom improvement. At the end of the study, about three-quarters of participants in the Arthro-7 group reported overall symptom relief, compared with only 16.3% in the placebo group (Table 6).

Discussion

Osteoarthritis is a common chronic disease affecting major segments of the population who are over middle age.¹⁶ Routine therapies, such as NSAIDs, for osteoarthritis are useful, but can also lead to adverse effects and complications over long-term administration.¹⁷ This study was designed as a double-blind, randomized, controlled trial to determine whether daily administration of the alternative dietary supplement, Arthro-7, could relieve symptoms in osteoarthritis patients with mild to moderate arthralgia.

As previously outlined, Arthro-7 is composed of a mixture of ingredients including vitamin C, collagen (from chicken), CMO, lipase, MSM, curcumin, and bromelain (Table 1).

Collagen – the main component of articular cartilage and the principal substance responsible for maintaining the physical, chemical, and mechanical properties of articular cartilage – accounts for about 85% to 90% of the Arthro-7. The collagen (from chicken) (CC) in Arthro-7 is extracted from chicken breast bone, which has previously been shown to suppress collagen-induced arthritis.¹⁸ In that study, Garcia et al showed that CC could suppress the body's autoimmune response and postpone the degradation of cartilage by inducing immuno-tolerance.¹⁸ In another study, patients diagnosed with rheumatoid arthritis treated with CC showed pronounced improvement of their disease symptoms.¹⁹ These results may be attributed to the similarity between osteoarthritis and rheumatoid arthritis in terms of pathogenesis and pathological changes, such as the induction of autoimmune responses, arthromeningitis, and over destruction of the articular cartilage. Using rat models of osteoarthritis, some studies have found that CC may correct the imbalance between cartilage matrix-degrading enzymes and the enzymes inhibitors, thus delaying the degradation of cartilage.²⁰ Other individual components in Arthro-7 such as MSM, lipase, bromelain, curcumin, and vitamin C have been individually shown to help relieve symptoms of osteoarthritis.^{21,22}

Table 4 Comparison of symptom scores before and after the intervention

Symptom [†]	Arthro-7 [®]		Placebo	
	t-statistic [‡]	P	t-statistic [‡]	P
Arthralgia	5.7041	<0.0001	-0.5727	0.5700
Anchylosis	3.4868	0.0022	-1.0000	0.3232
Arthroncus	2.1602	0.0425	–	–
Walking problem	2.8062	0.0106	–	–
Difficulty in getting up from bed	1.0000	0.3287	–	–
Difficulty descending stairs	2.9823	0.0071	-0.6279	0.5336

Notes: [†]Symptom scores ranged from 0 to 4, using the modified WOMAC[®] 3.1 questionnaire; [‡]paired t-test was applied to compare the symptom scores before and after the intervention. Some of the of the t-statistics could not be performed because the standard error of the difference was 0.

Table 5 Comparison of individual changes between the two groups

Symptom [†]	Score reduction difference [‡]	P	95% CI
Arthralgia	0.911	<0.001	0.594 to 1.228
Anchylosis	0.548	<0.001	0.303 to 0.792
Arthroncus	0.182	0.004	0.061 to 0.303
Walking problem	0.273	<0.001	0.133 to 0.412
Difficulty in getting up from bed	0.045	0.169	-0.020 to 0.111
Difficulty descending stairs	0.593	0.001	0.257 to 0.930

Notes: [†]Symptom scores ranged from 0 to 4, using the modified WOMAC[®] 3.1 questionnaire; [‡]linear regression was applied in comparing the differences of score reduction between the two intervention groups.

Abbreviation: CI, confidence interval.

Table 6 Self-reported symptom improvement over the study period (%)

	2 weeks	4 weeks	8 weeks	12 weeks
Arthro-7 [®]	39.2	45.1	60.8	74.5
Placebo	0.0	4.1	6.1	16.3

This study showed that Arthro-7 could remarkably alleviate joint pain in osteoarthritis patients. As mentioned in the results section, after a 12-week intervention, five of the six symptoms this study focused on were significantly relieved by Arthro-7 and the mean arthralgia scores were found to decrease by 0.911 points more in the Arthro-7 group than in the placebo group. Moreover, 74.5% of participants in the Arthro-7 group had experienced overall symptom relief by the end of the study period (12 weeks), compared with <20% in the placebo group. Together, these findings strongly indicate that Arthro-7 is very effective at relieving osteoarthritis-related symptoms.

Further, in this study, Arthro-7 was very effective at relieving ankylosis and improving the ability of osteoarthritis patients to descend stairs. The use of Arthro-7 was found to cause a reduction of 0.548 and 0.593 points more than taking the placebo for the symptoms of ankylosis and difficulty descending stairs, respectively.

Arthro-7 also showed statistically significant effects at relieving arthroncus and improving walking difficulties, although the magnitudes were considerably limited (a reduction of 0.182 and 0.273 points, respectively).

For difficulty getting up from bed, the difference between the two groups was very limited. There was insufficient evidence to distinguish the effects of Arthro-7 from placebo for this symptom.

In this study, the effect estimates of Arthro-7 were investigated in terms of individual level of magnitude and overall improvement rate, as we believe both aspects are equally important in decision-making. Combining these two aspects, especially when they are consistent, could enhance our confidence of determination of the effect of Arthro-7 in relieving symptoms of OS.

As in many randomized, controlled studies, we followed intent-to-treat policy, ignoring nonadherence. Subjects were compared based on initial randomization intervention groups. This method allowed us to avoid potential biases in comparison based on per-protocol analysis, since there was no evidence to suppose nonadherence was randomly distributed, though this method might lead to underestimation of the effect size.

Limitations

There were several limitations in this study. First, objective indicators such as blood samples, which can monitor the changes in cytokines associated with inflammatory responses, were not collected during the study period. The addition of these measurements to future studies may aid in determination of the mechanisms responsible for the anti-inflammatory effect of Arthro-7.

Second, since the study tested Arthro-7 as a single agent, it is not possible to attribute the effect to a specific ingredient of the compound, as the study only tested Arthro-7 as an existing single nutritional supplement, not the individual ingredients within it.

Third, although bromelain, antibiotics, or antiplatelet/anti-inflammatory agent (eg, NSAID) takers were excluded, there were still some potential confounding factors, such as weight, lifestyle, diet, and other drugs or supplements, that were not controlled for in our study. However, as the two groups were well balanced at baseline, we decided that the effects of differences in dietary intake or other potential confounding factors would be minimal.

Moreover, the results are only applicable to the sample range in this study, and should not be generalized to populations outside the sample range, as there may be a generalizing problem. Further study is therefore needed to confirm whether Arthro-7 is similarly efficacious in other populations.

Another limitation of the study was the use of a questionnaire to collect baseline information, as this relied on participants' recall. Thus, the results from this part may be prone to recall bias.

Finally, all our participants were volunteers; any eligible persons who did not wish to participate were excluded. If those who were excluded were not exactly compatible with those enrolled for the study, the results would suffer a selection bias.

Conclusion

In summary, our study showed that Arthro-7 has potent effects at relieving joint pain, ankylosis, and improving difficulty descending stairs in osteoarthritis patients. The effects on arthroncus and walking difficulties were limited, but statistically significant. These factors and results may assist physicians in determining Arthro-7's clinical applications and significance.

Disclosure

Mina Shariff, Kenneth Kami, and Pingping Gu are current or previous employees of DRM Resources, which sponsored this

project. The supplier of the Arthro-7 and placebo capsules, Robinson Pharma, had no role in the design or conduction of the study; the collection, management, analysis and interpretation of the data; or the preparation, review, and approval of this paper for publication. The other authors have no conflicts of interest in this work.

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