PILOT EXPERIMENTAL STUDY AFTER SURGERY ON THE USE OF A FOOD SUPPLEMENT IN ATHLETES FOR THE PROTECTION OF KNEE ARTICULAR CARTILAGE. A FUNCTIONAL AND BIOCHEMICAL STUDY.

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Arch Med Deporte 2021;38(3):168-172

INTRODUCTION

In this double-blind experimental study, the efficacy of chondroprotective supplementation, CarticurePlus®, its evaluated in patients with pathology of the anterior cruciate ligament (ACL) and meniscopathy that have required arthroscopic surgery. The goal of surgical intervention is to stabilize the articulation in order to try to stop the development of the degenerative changes in said joint, that is, the development of Articular Osteoarthritis (AO). The incidence of development of osteoarthritis after reconstructions of ACL and meniscal repair is high.

MATERIAL AND METHODS

Experimental, double-blind study with two arms of random assignment of treatment (CarticurePlus® vs. placebo), in which the effects on pain and different systemic markers are analyzed in 24 amateur athletes between 30 and 50 years. These patients are selected stratifying in 12 patients with meniscopathy and 12 patients with ACL ligamentous injury, who were practiced arthroscopic surgery to later take 1 sachet per day of CarticurePlus® (bioactive collagen peptides 5000 mg, chondroitin sulfate 1200 mg, glucosamine hydrochloride 1500 mg, vitamin C 80 mg, manganese 2 mg and copper 1.1 mg) versus placebo for three months.

The variables of the study were the measurement, through ELISA test, of different markers in blood: pro-inflammatory/catabolic (PCR, IL-6, IL-1β, TNF-α), anabolic (TGF-β and FGF-21), collagen 2A and hyaluronic acid. Also various scales and questionnaires were measured, that assessed pain, functionality and quality of life: the Visual Analog Scale (VAS) to assess pain; the WOMAC questionnaire (Western Ontario McMaster Universities Osteoarthritis Index) made up of three subscales measuring pain, stiffness, and functional capacity and the KOOS scale (Knee Injury and Osteoarthritis Outcome Score) that measures various aspects such as symptoms, stiffness, pain, daily activities, sport and recreational activities and quality of life.

The values of systemic markers and the WOMAC scale are collected and compared in the two treatment groups at the baseline and final visit; and the Visual Analog Scales and KOOS between the baseline visit and the first visit (1 month), second visit (2 months) and third visit (3 months).

RESULTS

Regarding the inflammatory markers, of anabolism and articular catabolism in the two pathologies, statistically significant differences have not been found. Neither in the EVA.

There is an improvement in the functional capacity of the WOMAC scale in the group of patients taking CarticurePlus® vs. placebo between the baseline and final visit. The pain dimension for the same scale is close to a statistically significant difference, not observing differences in the stiffness subscale.

We observed statistically significant differences in the improvement of the CarticurePlus® group compared to placebo in the activity of daily living subscale (KOOS) between baseline visit and first visit in meniscal pathology. This difference is maintained between the baseline visit and the second visit in this pathology.

There are also statistical differences significant in favor of CarticurePlus® on the subscale of sports and recreational activities (KOOS) in pathology meniscal between the baseline visit and the first visit. Also, we detected statistically significant differences in the CarticurePlus® group versus placebo for the quality of life subscale (KOOS) between baseline visit and the first visit in ligamentous pathology. In this last pathology, pain improvement is also observed in the CarticurePlus® group versus placebo between the second month and the baseline. If we consider all patients regardless of the type of pathology, an improvement in pain (KOOS subscale) between the baseline visit and the first visit in favor of CarticurePlus® versus placebo is observed, and also an improvement in activities of daily activity between baseline visit and visits made at one, two and three months.

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CONCLUSION

In clinical data, despite the small sample size, statistically significant differences of clinical improvement in favor of CarticurePlus® are observed, compared to placebo.

During the first month an improvement in the KOOS scale is observed (Figures 1-4). This makes possible to detect trends in a faster improvement, which equalizes after three months in the case of ligamentous injury, but that in the case of meniscal clinical improvement is maintained in the CarticurePlus® group.

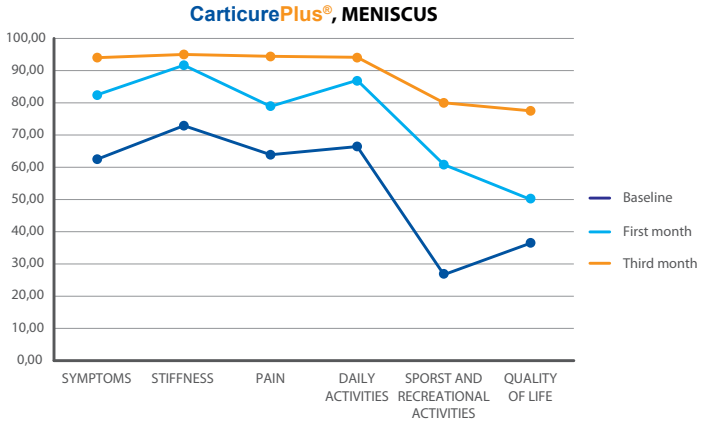

Figure 1. Evolution of the KOOS questionnaire, baseline, one month and three months in patients who took CarticurePlus® with meniscus pathology.

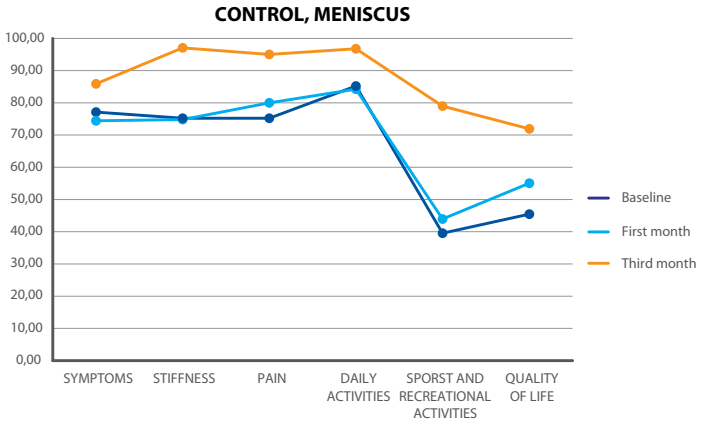

Figure 2. Evolution of the KOOS questionnaire, baseline, one month and three months in patients in placebo group with meniscus pathology.

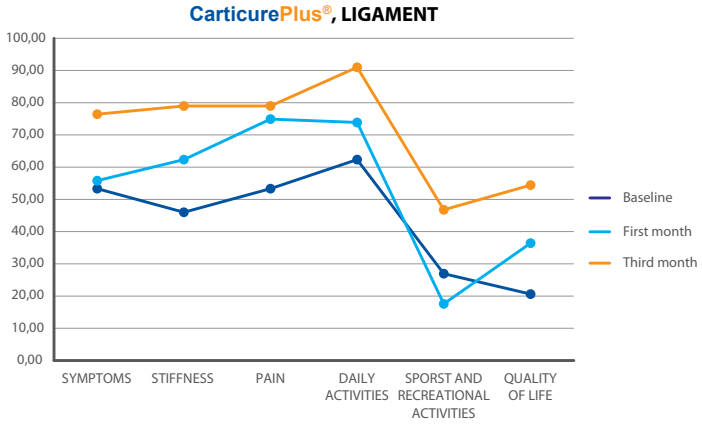

Figure 3. Evolution of the KOOS questionnaire, baseline, one month and three months in patients who took CarticurePlus® with ligament pathology.

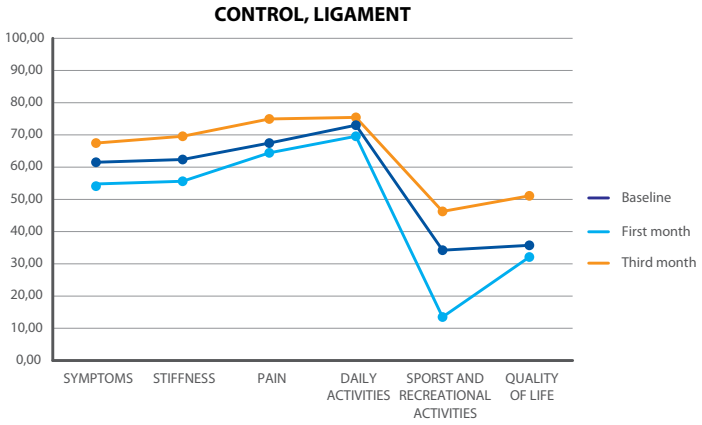

Figure 4. Evolution of the KOOS questionnaire, baseline, one month and three months in patients in placebo group with ligament pathology.

Statistically significant differences have also been observed in activities of daily living, sport activities and recreational activities in meniscal injury between the baseline visit and the first month, and in the quality of life in ligamentous pathology between baseline visit and the first month. In the group of 24 patients, the improvement in pain at one month and the improvement of activities of daily living at one, two and three months indicates that the fastest improvement associated with CarticurePlus® produces a sustained recovery that lasts three months in the absence of the food supplement, which can be explained by the characteristics of the product.

It is remarkable the fact of having found statistically significant differences with so few cases (12 patients in each pathological group) which favors the clinical assessment of improvement in the first month of CarticurePlus®.

Therefore, we can conclude that **the incorporation of CarticurePlus® for three months, after a surgical intervention** of the meniscal or ligament pathology, **will rapidly improve** the first month clinic and this will allow better values in terms of daily life activity in all patients at three months.

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