Functional Improvement and Safety of a Multicomponent Formulation Containing Undenatured UC-II® Collagen, Magnesium, Boswellia Serrata, and Turmeric in Patients with Joint Disorders (FISMFJD)

First published: 23/06/2026

Last updated: 23/06/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000001035

Study ID

1000001035

DARWIN EU® study

No

Study countries

Spain

Study description

Objective: To evaluate the clinical efficacy, safety, and longitudinal functional response of a multicomponent dietary supplement (Artiok®) in patients with musculoskeletal pathology under routine, real-world clinical conditions.
Methods:This was a prospective, multicentre, observational real-world evidence study. A single initial cohort of 289 patients with chronic joint pain and functional limitation was enrolled. Outcomes were assessed at baseline (V1) and 30 days (V2) for the full cohort (n=289), and at 90 days (V3) for the patients who completed the full longitudinal protocol (n=190). Outcomes were quantified using a validated 24-item WOMAC-based questionnaire converted to a 0–4 Likert scale. Statistical analysis was performed using non-parametric paired Wilcoxon Signed-Rank tests and Mann-Whitney U tests for independent cohorts.
Results:For the longitudinal completers (n=190), continuous supplementation yielded a 48.54% reduction in the Total WOMAC score and a 51.11% reduction in global pain at 90 days ($p < 0.001$). Significant biomechanical restoration was observed; functional difficulty getting in and out of a vehicle decreased by 52.86%, while pain descending stairs improved by 47.24% ($p < 0.001$). The formulation also attenuated resting inflammation, reducing nocturnal pain by 48.80% and morning stiffness by 46.90%. Notably, a secondary analysis revealed that patients managing pain exclusively with the supplement achieved a 52.36% pain reduction, statistically comparable to those requiring concomitant NSAIDs or rescue analgesics (47.34%, $p = 0.285$). Regarding safety, zero adverse events (0%) were reported across the entire enrolled cohort of 289 patients.
Conclusion:Supplementation with the multicomponent Artiok® formulation is associated with clinically and statistically significant improvements in pain and functional autonomy in a real-world setting.The synergistic mechanism offers rapid symptomatic relief, making it a viable strategy for joint management.

Study status

Finalised

Research institutions and networks

Institutions

BIOKSAN

Spain

First published: 17/06/2026

Last updated: 17/06/2026

Institution **Laboratory/Research/Testing facility**

Contact details

Study institution contact

Javier García Perez Delabat jdelabat@bioksan.com

Study contact

jdelabat@bioksan.com

Primary lead investigator

Miguel Dominguez Meléndez 0000-0002-1431-7223

Primary lead investigator

ORCID number:

0000-0002-1431-7223

Study timelines

Date when funding contract was signed
Planned: 17/01/2022

Actual: 25/01/2022

Study start date
Planned: 02/02/2022

Actual: 02/02/2022

Date of final study report
Planned: 08/06/2026

Actual: 08/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bioksan Naturalmente Juntos SL

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Herbal medicinal product

Study topic, other:

Nutraceutical product

Study type:

Not applicable

Scope of the study:

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

If ‘other’, further details on the scope of the study

Prospective Real-World Observational Study

Data collection methods:

Primary data collection

Study design:

An observational, prospective, and multicentre study was conducted under real-world clinical practice conditions. The primary objective was to evaluate the clinical and functional response of patients with musculoskeletal disorders (predominantly osteoarthritis) following daily Artiok supplementat.

Main study objective:

The primary endpoint was the change in the Total WOMAC score, alongside its specific Pain and Physical Function subscales, from baseline (V1) to the final 90-day follow-up (V3) for the patients completing the longitudinal protocol.

Secondary endpoints included the short-term therapeutic response evaluated at

30 days (V2) for the full enrolled cohort. Additional secondary assessments included the evolution of the joint stiffness subscale, the restoration of specific biomechanical activities of daily living (such as descending stairs), and the overall safety and tolerability of the formulation throughout the observational period.

Study drug and medical condition

Medicinal product name, other

Artiok

Medical condition to be studied

Osteoarthritis

Population studied

Short description of the study population

To preserve the ecological validity of this real-world study, patient selection was designed to be pragmatic and reflective of routine clinical practice. A total of 289 patients who attended rheumatology, traumatology, or primary care consultations were included.

Eligible participants comprised patients (aged ≥14 years) with a clinical diagnosis of chronic degenerative joint disease or osteoarthritis, characterized by persistent joint pain and functional limitation for a minimum of three months. In order to capture a truly representative demographic, strict radiological cut-offs (such as specific Kellgren-Lawrence grades) or body mass index (BMI) restrictions were not mandated, as these are rarely required prior to

nutraceutical prescription in standard outpatient care.

Exclusion criteria comprised acute inflammatory articular processes of infectious or autoimmune origin (e.g., rheumatoid arthritis), severe cognitive impairment precluding accurate questionnaire completion, or specific contraindications to any component of the formulation.

To evaluate both the early clinical response and the sustained longitudinal efficacy of the intervention, follow-up visits at two different time points were scheduled. All 289 patients completed the baseline (V1) and 30-day short-term evaluation (V2). Of this initial cohort, 190 patients completed the full longitudinal protocol, returning for the 90-day assessment (V3), representing a retention rate of 65.7% (Figure 1). The remaining 99 patients were lost to follow-up after the 30-day visit. Data from the full cohort (n=289) were used to assess early therapeutic response, while data from the completers (n=190) were used to evaluate sustained, long-term efficacy.

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)

        - Adults (46 to < 65 years)
    - Elderly (≥ 65 years)
        - Adults (65 to < 75 years)
        - Adults (75 to < 85 years)
        - Adults (85 years and over)

Estimated number of subjects

289

Study design details

Interventions

All patients received oral supplementation consisting of one daily capsule of Artiok® during the period between the baseline visit and final assessment. The specific composition per dosage unit included 40 mg of undenatured type II collagen (UC-II®), 56.10 mg of magnesium, 20 mg of Boswellia serrata, 10 mg of turmeric and 5 mg of hyaluronic acid. The formulation was further complemented with a vitamin matrix containing 40 mg of vitamin C, 5 µg of vitamin D3 and a B-vitamin complex composed of 4.8 mg of vitamin B1, 4.2 mg of vitamin B2, 6 mg of vitamin B6 and 2.5 µg of vitamin B12, together with 1 mg of black pepper to optimise compound bioavailability. Consistent with the real-world observational design of the study, patients were permitted to utilize standard analgesic or non-steroidal anti-inflammatory drugs (NSAIDs) as rescue medication. All concomitant pharmacological treatments were systematically recorded at each timepoint to enable a stratified analysis of the supplement's intrinsic efficacy independent of standard palliative care.

Comparators

At each visit, the validated Spanish version of the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) questionnaire was used for patient assessment. (Bellamy et al., 1988; Escobar et al., 2002) Responses were originally collected qualitatively (“None”, “Mild”, “Moderate”, “Severe”, “Extreme”) and subsequently converted for statistical analysis into a 0–4 ordinal Likert-type scale, where 0 represented “None” and 4 represented “Extreme”. The evaluated item outlines the domains of pain, stiffness and functional capacity. Analysed variables included:

• Joint pain: Evaluated in different situations (at rest, at night, when walking on flat ground, and when climbing or descending stairs).
• Stiffness: Assessed after waking and following periods of inactivity during the day.
• Functional capacity: Difficulty performing activities of daily living, such as bending down, getting in and out of a vehicle, or carrying out household tasks.
• Safety and satisfaction: Recording of adverse effects and overall satisfaction of both patients and healthcare professionals at study completion.

Outcomes

The present real-world observational study demonstrates that continuous supplementation with the multimodal formulation Artiok® represents a effective and safe therapeutic strategy for the management of chronic musculoskeletal joint degeneration. Over a 90-day period, patients achieved functional restoration, evidenced by a nearly 50% reduction in their Total WOMAC scores and a halving of global joint pain.

Crucially, the benefits of the intervention extended far beyond basic locomotion. The formulation significantly restored physical independence in biomechanically demanding tasks (such as eccentric joint loading and deep

lower-limb flexion), while simultaneously attenuating resting inflammatory symptoms, including nocturnal pain and morning stiffness. Furthermore, the analysis of patient attrition highlighted a critical clinical insight: early therapeutic response at 30 days is a primary driver of long-term adherence, underscoring the need for physicians to actively manage patient expectations regarding the cumulative nature of chondroprotective therapies.

Ultimately, given its synergistic efficacy and the complete absence of adverse events, Artiok® offers a favourable long-term tolerability profile compared to traditional chronic NSAID therapy. Furthermore, its standalone analgesic capacity proved statistically comparable to the use of concomitant rescue medications, highlighting its robust potential as a safe, NSAID-sparing alternative. It stands as a valuable, foundational intervention for restoring patient autonomy and quality of life in routine rheumatological and traumatological clinical practice.

Data analysis plan

Data were processed using the Python programming language (version 3.10+). Given the observational real-world design of the study, no formal a priori sample size calculation was performed. Nevertheless, the initial inclusion of 289 patients provided substantial statistical power for longitudinal analyses and allowed for the robust detection of clinically relevant within-subject changes over time.

Due to the ordinal nature of the Likert-scale variables and the absence of an assumed normal distribution, the non-parametric Wilcoxon Signed-Rank (WSR) test was utilized to evaluate paired mean differences between baseline and follow-up assessments. Specifically, paired analyses were conducted comparing V1 versus V2 (30-day response), and V1 versus V3 (90-day response for the

longitudinal completers). Additionally, for the secondary stratified analysis comparing the percentage of pain improvement between independent patient subgroups (those using concomitant rescue medication versus those managed exclusively with the study supplement), the non-parametric Mann-Whitney U test was employed. A confidence level of 95% was established, and differences with a p-value < 0.05 were considered statistically significant.

To quantify the magnitude of the clinical improvement, effect sizes were calculated using Cohen's d. The thresholds for interpretation were defined a priori as small (d = 0.2–0.5), medium (d = 0.5–0.8), and large (d > 0.8). (Cohen, 2013) Additionally, to ensure the robustness of the findings despite the observational attrition, a post-hoc statistical power analysis was conducted based on the final sample size of the longitudinal cohort (n=190) and the primary effect size.

Summary results

For the longitudinal completers (n=190), continuous supplementation yielded a 48.54% reduction in the Total WOMAC score and a 51.11% reduction in global pain at 90 days ($p < 0.001$). Significant biomechanical restoration was observed; functional difficulty getting in and out of a vehicle decreased by 52.86%, while pain descending stairs improved by 47.24% ($p < 0.001$). The formulation also attenuated resting inflammation, reducing nocturnal pain by 48.80% and morning stiffness by 46.90%. Notably, a secondary analysis revealed that patients managing pain exclusively with the supplement achieved a 52.36% pain reduction, statistically comparable to those requiring concomitant NSAIDs or rescue analgesics (47.34%, $p = 0.285$). Regarding safety, zero adverse events (0%) were reported across the entire enrolled cohort of 289 patients

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

Bioksan

Data sources (types)

Patient surveys

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No