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A new nutrient mix with omega-3 fatty acids, collagen and astaxanthin for the management of knee osteoarthritis

Submission date
10/11/2026

Recruitment status
No longer recruiting

Registration date
10/11/2026

Overall study status
Completed

Last Edited
10/11/2026

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Knee osteoarthritis is a major cause of joint pain and walking difficulties, especially for individuals over the age of 40 years. While typical pain medications can offer temporary relief, they often carry a risk of side effects and do not support joint health long-term. This study evaluates a commercial dietary supplement called Sienna® SPMs, which combines specific natural active ingredients (specialized pro-resolving mediators, omega-3 fatty acids, undenatured native type II collagen, and astaxanthin) intended to reduce inflammation, protect cartilage, and provide antioxidant support.

Who can participate?
Men and women aged between 40 and 80 years old with early-to-moderate knee wear and tear (Grade 1 or Grade 2 knee osteoarthritis) in one or both knees

What does the study involve?
This is an observational, real-world study lasting exactly 3 months (90 days) per patient, integrated smoothly into regular private medical checkups. Participants take one capsule orally once a day with breakfast under their doctor's supervision. There are three key milestones:
Initial visit (day 0): The participant reviews and signs consent and privacy forms. The doctor logs basic medical history (age, gender, existing medical conditions, and current pain meds) securely into a mobile app or desktop portal. The patient completes baseline pain and mobility questionnaires.
Interim check (day 30): The doctor verifies regular supplement use and notes any shifts in routine pain medication. The patient completes a mid-point joint assessment and an intermediate satisfaction questionnaire.
Final assessment (day 90): The patient completes final joint questionnaires assessing total progress and overall satisfaction. The doctor logs their closing professional views on the supplement's performance and records whether they intend to prescribe it in the future.

What are the possible benefits and risks of participating?
Participants may see structural support for joint comfort, decreased stiffness, and improved

daily mobility. Tracking your symptoms closely with a specialist can also optimize your overall knee care plan, potentially lowering the need for conventional anti-inflammatory drugs. Because this is a non-interventional observation of an approved, commercially available dietary supplement, risks are minimal. However, as with any supplement, some individuals might experience mild, temporary reactions such as skin itching, hives, headaches, or slight drowsiness. Any such symptoms are immediately reported by the doctor through a formal safety reporting system.

Where is the study run from?
Exeltis Pharma México

When is the study starting and how long is it expected to run for?
August 2025 to August 2026

Who is funding the study?
Exeltis Pharma México

Who is the main contact?
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Study information

Scientific Title
An observational, prospective, longitudinal, uncontrolled study in patients over 40 years of age with knee osteoarthritis (grades 1 and 2), using a dietary supplement containing specialized pro-resolving mediators, omega-3, undenatured native type II collagen and astaxanthin to assess changes in clinical signs and symptoms, patient tolerability and acceptability, and the clinician's opinion, within routine clinical practice

Acronym
Sienna 0.1

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/06/2025, Research Ethics Committee, La Mision Hospital (Del Hospital 112, 1° y de 2° Piso, Oficina 204. Col. Sertoma., Monterrey, 64718, Mexico; +52 (0)811492 4050; nvesligacion@hospitallamision.com), ref: 31.- 20250604

Primary study design
Observational

Secondary study design
Case-control study

Study type(s)

Health condition(s) or problem(s) studied

Knee osteoarthritis (OA)

Interventions

Doctors will be invited to participate in the PET via a Letter of Invitation to the Doctor (Form 1), which will be delivered in person or digitally by EPM's sales department. Healthcare professionals who decide to participate in the PET will be registered on the app based on the list provided by EPM to the company contracted for this activity and will confirm their details using (Form 2), which will include the following information:

1. Full name
2. Specialism
3. Professional registration number
4. Email
5. Office telephone number
6. Mobile

The sales team and the company contracted for this activity will train healthcare professionals who have agreed to take part in the programme on how to use the app.

Once doctors have been trained and registered on the app and log in for the first time, they must verify that their information is correct (Form 2) and confirm their acceptance. If the information is incorrect, the doctor may amend it and, once the change has been made, must confirm their acceptance.

Similarly, they must accept the Privacy Notice for doctors (Form 3) regarding the protection of their personal data, which will be available on the app; if necessary, EPM's sales team can provide the doctor with a printed copy of the form.

It is estimated that each doctor will enrol and monitor 8 patients in accordance with the instructions in the 'Patients' section of this protocol; these patients must attend 3 follow-up visits (initial visit on day 0, interim visit on day 30 and final visit on day 90). A total of 800 patients will be enrolled over an estimated period of 3 months.

If patients agree to take part in the PET, they must complete and accept the Informed Consent Form for patients (Form 4), which is available on the app and requires the following information:

1. Full name, address and contact details of two witnesses, who must be relatives or acquaintances of the patient
2. The patient's full name, address and contact details
3. Full name, address and contact details of the doctor

Once signed, the above form (Form 4) will be sent to the patient, the doctor and the company contracted to carry out this PET.

Healthcare professionals will instruct patients to start taking the dietary supplement.

During the initial consultation, the doctor will register each patient on the app. Patients, via their doctor, must:

1. Accept the Privacy Notice for patients (Form 5)
2. Complete the requested information at each visit
3. Complete a questionnaire to assess the product's efficacy using the validated WOMAC scale
4. Questionnaire to assess pain reduction using the Visual Analogue Scale (VAS)

5. Record of NSAID requirements
6. Questionnaire assessing patients' acceptance of the dietary supplement (interim visit on day 30 and final visit on day 90)
7. Report on adverse effects of dietary supplements

Participating doctors and discharged patients will be recorded on Forms 6 and 7, respectively.

Healthcare professionals will be responsible for monitoring and tracking the progress of each of their patients, in accordance with their usual clinical practice, throughout the 3-month duration of this PET.

Patients will attend three appointments: an initial appointment (day 0), an interim appointment (day 30) and a final appointment (day 90) during the course of this PET.

During these visits, healthcare professionals will be able to access, via the app (iOS and Android) or website, the specific questionnaires to be used at the initial and follow-up visits (Forms 8–12) to record their patients' initial and follow-up information. These forms are listed below:

Medical history forms:
Initial medical history (healthcare professionals, initial visit, day 0):
1. Identification form: Initials, age and gender
2. Diagnosis: Grade 1 and 2 knee osteoarthritis, unilateral or bilateral
3. Family history of knee osteoarthritis of any type
4. Concomitant conditions
5. Pharmacological treatment with NSAIDs or other anti-inflammatory medicines for osteoarthritis
6. Other concomitant medications
7. Other information (physical activity)
8. Date on which the dietary supplement was first taken
9. Date of next visit (interim visit)

Interim and final medical records (healthcare professionals, interim visit on day 30 and final visit on day 90): the follow-up information will be the same as that specified by the doctor at the initial visit and will be automatically uploaded for consultation; only the pharmacological treatment with NSAIDs and the date of the next visit (final visit) will be added.
1. Identification details: Initials, age and gender.
2. Diagnosis: Grade 1 and 2 knee osteoarthritis, unilateral or bilateral
3. Family history of knee osteoarthritis of any type
4. Concomitant conditions
5. Pharmacological treatment with NSAIDs or other anti-inflammatory medicines for osteoarthritis
6. Other concomitant medications
7. Other information (physical activity)
8. Date on which the dietary supplement was first taken
9. Date of next visit (Final visit)

Patient forms to be completed via the doctor (initial visit on day 0, interim visit on day 30 and final visit on day 90):
1. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)
2. Visual Analogue Scale (VAS) for pain

Interim and final questionnaires on doctors' opinions and patient acceptability:
1. Questionnaire assessing patient acceptability of the dietary supplement (interim visit on day 30 and final visit on day 90)
2. Questionnaire assessing doctors' views on the dietary supplement (interim visit on day 30 and final visit on day 90)

Adverse event report for dietary supplements (safety information report form)
Withdrawal or termination form
Technical support form

The information captured via the app (iOS and Android) or website will be collated in a database, which will be monitored and analysed by the company contracted by EPM for this activity.

Patients must inform their doctor of any side effects they experience, and the doctor must complete Form 11, which can be found on the app and website, as soon as they become aware of the case.

Any reports of side effects received via the app and website will be forwarded by the company contracted for this purpose to EPM's Pharmacovigilance Unit for internal assessment.

During follow-up visits at 30 and 90 days after the start of treatment, patients, via their healthcare professionals, must complete the questionnaire assessing patient acceptability of the dietary supplement (Form 10.1), which is available on the app or website.

During the follow-up visits at 30 and 90 days, healthcare professionals must complete the questionnaire assessing doctors' views on the food supplement (Form 10.2).

Once the follow-up period has ended for all patients included in this PET, the company contracted for this activity and EPM will analyse the results obtained and use them for the purposes required by EPM.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Dietary supplement containing specialized pro-resolving mediators (SPMs), Omega-3, undenatured native type II collagen (UC-II) and astaxanth

Primary outcome(s)
1. Clinical signs and symptoms measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at 12 weeks

2. Pain, stiffness and functional ability measured using the Visual Analogue Scale (VAS) at 12 weeks

3. Need for NSAIDs measured using medical records at 12 weeks

Key secondary outcome(s)

1. Tolerability of the product measured using the occurrence of any potential side effects at 12 weeks

2. Clinicians' opinions and patients' acceptance of the dietary supplement measured using survey at 12 weeks

Completion date
31/08/2026

Eligibility

Key inclusion criteria
1. Patients who meet the diagnostic criteria for grade I and II osteoarthritis (Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC] questionnaire score of 8 to 50) and/or at the clinical discretion of their treating doctor
2. Male and female patients aged between 40 and 80 years
3. Patients who sign an informed consent form
4. Patients must be able to walk
5. Willingness to participate in follow-up for the duration of the 3-month study
6. If you use physical therapies, thermotherapy or exercise as an adjunct to treatment, you must continue with these during the study so as not to alter the baseline conditions
7. If you are using any non-steroidal anti-inflammatory drugs (NSAIDs) as an adjunct, you may continue to do so

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
460

Key exclusion criteria
1. The patient is currently taking, or is due to take, any chondro-modulators or collagen (e.g., glucosamine and chondroitin, diacerein, Persea gratissima and Glycine max, type I and type II collagen, hydrolysed and non-hydrolysed, oral hyaluronic acid and curcumin)
2. The patient has undergone viscosupplementation, arthrocentesis or any surgical treatment within the last 6 months

3. The patient refuses to participate for any reason
4. Patients with a history of recent trauma
5. Patients with any contraindication attributable to the food supplement or any of its excipients

Date of first enrolment
01/08/2025

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
Mexico

Sponsor information

Organisation
Exeltis Pharma México

Funder(s)

Funder type

Funder Name
Exeltis Pharma México

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available