SY11

IS THERE A RESPONDER PROFILE TO PHARMACEUTICAL-GRADE CHONDROITIN SULFATE? AN ANALYSIS OF THE CONCEPT STUDY

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In the CONCEPT study (Reginster J-Y, Dudler J, Blicharski T, et al. Ann Rheum Dis 2017;76:1537–1543) 800 mg/day of pharmaceutical-grade Chondroitin Sulfate (CS) was shown to be superior to placebo and similar to celecoxib in reducing pain and improving function over 6 months in patients with symptomatic knee osteoarthritis (OA). We investigate, in the present study, whether a responder profile to CS could be defined, i.e. to determine a patient's profile with the best response to the treatment. Subjects from the CS group of the CONCEPT study were included in the present analysis. Within the CS group, various groups were created based on different categories of age, sex, BMI, Kellgren & Laurence severity, age since OA and baseline level of pain/function. The non-parametric Kruskal-Wallis (KW) test was applied to compare the VAS Pain/Lequesne Index evolutions between groups and the Dwass, Steel, Crichlow-Flinger (DSCF) procedure was used to compute multiple comparisons. The impact of various covariates on the VAS Pain/Lequesne Index evolution was assessed by means of a multiple regression. The probability to respond to CS treatment was significantly associated with the duration between the date of diagnostic and the initiation of the treatment: higher the duration, lower the response both for pain and function, particularly for patients with duration >10 years as compared to patients with duration <5 years. A significant effect of the baseline function on the improvement of the Lequesne Index is also observed, with a highest response in patients with the lowest function at baseline. No other criteria have been found to be associated with the response to CS treatment in the CONCEPT study.

SY12

CS PHARMACEUTICAL GRADE AND CS NUTRACEUTICALS HOW FAR ARE THEY?

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Objectives: Chondroitin sulfate is a symptomatic slow-acting molecule recommended by ESCEO for the treatment of osteoarthritis. It is commercialized as pharmaceutical grade product and as food supplement in combination with other components (e.g. methylsulfonylmethane, plant extracts, vitamins, collagen etc.). Food supplements do not need to undergo the strict regulatory controls of pharma grade products, thus composition and the eventual presence of contaminants may not be evidenced before commercialization. Concerns should rise on the biological efficacy of these formulations. In this research a systematic multi-analytical approach was designed to analyze over 25 different food supplements from 8 diverse European countries, in comparison to pharmaceutical grade samples.

Methods: Strong anion exchange chromatography, high performance capillary electrophoresis, size exclusion chromatography coupled to laser scattering detector and finally heterocorrelated NMR technique were used to evaluate: a) content and purity of CS b) presence of Keratan Sulfate (KS) as contaminant c) CS extractive source.

In vitro model based on human chondrocytes and synoviocytes were set up for bioactivity comparison, using time lapse video microscopy, and biomarkers quantifications via western blotting and ELISA assays.

Results: The analytical approach helped in assessing that the CS content in food supplements was lower than expected/declared. In addition KS accounted for up to 30% contamination of CS in food supplements. After the structural analysis, the biological efficacy of 5 food supplements was tested in comparison to pharmaceutical products. The results of an in vitro model on synoviocytes and chondrocytes cells, proved higher cell viability, proliferation and inflammation reduction (NF-kb mediated pathway) by the pharmaceutical products while the food supplements tested were not as effective. A couple of those appeared also cytotoxic.

Conclusions: Assessment of quality and purity of CS, beside the dosage is of key importance to find a robust correlation between treatment and clinical outcomes in OA patients.

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