

CHONDROPROTECTION THROUGH CHONDROITIN 4&6 SULPHATE (CONDROSULF®): THE ZURICH STUDY

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Aims:

The primary objective of this study was to assess the effect of chondroitin 4&6 sulphate (CS, Condrosulf®) as a Structure Modifying Drug in knee OA (SMOAD) measuring the progression of joint space minimum width, mean width and mean surface analysed by means of a validated automatic image analysis of digitized X-rays. The patient self-report on symptom severity and physical functional status, as measured with the WOMAC (Western Ontario and Mac Master Osteoarthritis Questionnaire), and the use of escape therapies were considered as secondary parameters. In addition, the assessment of the effects of CS on the evolution of spinal and femoral bone mineral density (BMD) in knee OA patients has also been evaluated.

Methods:

The trial was carried out at the University Hospital in Zurich, Switzerland as a single clinical center. This study was a randomised, double-blind, two-year prospective (Phase III) clinical trial comparing chondroitin 4&6 sulphate 800 mg/day (Condrosulf®) with placebo in patients with non-end stage OA of the knee. According to a sample size of at least 80 patients in each group who have to complete the two-year study, 300 patients of both gender, aged > 40 with clinically symptomatic knee OA, Kellgren & Lawrence score I-III, were recruited and randomly allocated to CS or PBO groups. X-rays of both knees were taken at entry and after 2 years in a posteroanterior weightbearing view with the knees flexed to 20° (Schuss position). The target knee was defined upon entry. X-rays were blindly evaluated at the end of the study using a validated digitized image analysis system. Spinal and femoral bone mineral density (BMD) was measured by DEXA upon entry, at month 12 and 24 using a Hologic R QDR-4500 densitometer.

Results:

Of the 300 patients, 219 completed the two-year treatment period. Measurements of femoro-tibial joint space (JS) of the target knee in Schuss position for per protocol (PP) patients having a minimum JS width ≥ 1 mm at entry were analysed. The minimum JS width, the mean JS width and the JS surface area did significantly decrease in the PBO group whereas they did not change in the CS group. The evolution was significantly different between groups for the minimum JS width and for the mean JS width. Data of the intention-to-treat (ITT) analyses did confirm these results. The clinical results as well as the spinal and femoral DEXA analysis will also be discussed.

Conclusion:

The measurement of the femoro-tibial joint space narrowing (PP and ITT) using quantitative digitized X-ray image analysis does confirm the efficacy of chondroitin 4&6 sulphate (Condrosulf®) in this two-year trial. Chondroitin 4&6 sulphate, a well-known Symptomatic Slow Acting Drug for the treatment of OA (SYSADOA), appears to qualify as a Structure Modifying Drug in the treatment of OA (SMOAD).



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