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P427FR. PROSTEP STUDY: PROTELOS® 2 G IN THE OSTEOPOROSIS TREATMENT, THE TOLERABILITY AND EFFICACY PROFILE

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Introduction: Osteoporosis has been an underestimated clinical entity so far, but in the near future it will surely be named among the modern epidemics of industrialized world. One of the major issues of the current pharmacotherapy of osteoporosis is a low adherence of patients to the treatment. Follow up by physicians to ensure adherence of the treatment is therefore as important as the antifracture efficacy.

Method: PROSTEP study PRotelos® 2 g (strontium ranelate, SR) in the OSteoporosis treatment, the Tolerability and Efficacy Profile open multicentric study in osteoporotic women. SR (2 g/d) was allocated to 125 osteoporotic women over 12 months follow up (FAS population). Primary endpoint was to evaluate adherence to treatment with SR by evaluation of compliance with persistence and improvement of quality of life by using visual analogue scale questionnaire (in Per protocol population PP). Secondary end points consisted of acceptability and clinical efficacy (lumbar spine/ total hip BMD T score between M0 and M12).

Results: Of the 125 women initially recruited (age >67 yr, age of menopause 47 yr, lumbar spine/total hip BMD T score 3.2 and 1.8/ SD resp., 70.4% out of them with prevalent osteoporotic fracture) 99 completed 1 year follow up (PP) with persistence to the treatment of 79.2%. Mean time for treatment discontinuation was 314 days (FAS) resulting in compliance of 97% over 12 months. The continual improvement in quality of life was observed from the first month of treatment, especially in terms of reporting less "middle back pain" and "upper back pain" by 32% ($p<0.001$) over one year. SR increased lumbar spine BMD by 8.6% (n 97) and total hip BMD by 5.2% (n 94, for both $p<0.001$). There was a low level of side effects. The most frequent were diarrhea and dyspepsia, detected for transient period in the beginning of treatment.

Conclusion: The PROSTEP study confirmed efficacy and tolerability of strontium ranelate in the treatment of osteoporosis, in accordance with results from large phase III trials. Good results in term of adherence and compliance to the treatment were related to strontium ranelate administrated as one sachet at bed time.