

## Abstract - Juni 2002

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A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, CROSS-OVER TRIAL OF THE HERBAL REMEDY HYPENVITAL IN PATIENTS WITH OSTEOARTHRITIS. Gorm Thamsborg, Karin Apel, Department of Rheumatology, Amtssygehuset i Glostrup, University of Copenhagen; Eydbjørg Rein, Institute for Clinical Research, Kolding. Kaj Winther, Department of Clinical Biochemistry, Amtssygehuset i Gentofte, Arsalan Kharazmi, Department of Clinical Microbiology, Rigshospitalet, University of Copenhagen, Denmark.

Alternative medicine is used extensively by patients with osteoarthritis. Only a few of these medications have been tested in a controlled setting. The present study was undertaken to examine the effect of the herbal remedy Hyben Vital, a standardised powder produced from seeds and shells of rose-hip (Rosa-Canina). Hyben Vital has been reported to inhibit certain leucocyte functions of potential relevance to inflammation.

METHODS: Seventy-six patients with osteoarthritis of either the hip or the knee, diagnosed according to the ACR-criteria, were included in a randomised, placebo-controlled, double-blind cross-over trial. Thirty-eight patients were given 5 Hyben Vital capsules 0,5 g twice daily, and 38 patients were given identical placebo capsules in the same dosage. After 3 month of treatment the group initially taking Hyben Vital was changed to placebo and vice versa. Symptoms were scored by the WOMAC-questionnaire (VAS 0 - 100 mm version), and calculatede as WOMAC-pain (mean of 5 questions), WOMAC-stiffness (mean of 2 questions), WOMAC-disability (mean of 17 questions), and WOMAC-patient global assessment of severity of the disease (1 question).

Chemotaxis of neutrophils was measured in a subgroup of 15 patients using a Boyden chamber assay. Data are given as medians (upper - lower quartiles). Non-parametric test was used. RESULTS: During treatment with Hyben Vital WOMAC-patient global assessment of severity of the disease and WOMAC-stiffness decreased significantly by 18.3 (0.9 - 33.9) and 6.5 (-7.9 - 22.9), respectively, as opposed to a decrease of 6.9 (-12.8 - 31.7) and 1.9 (-6.1 - 18.7), respectively, when placebo was given (p<0.04). WOMAC-disability decreased by 4.2 (-3.5 - 15.9) during treatment with Hyben Vital as opposed to a decrease of 0.9 (-7.7 - 14.5), when placebo was given (p=0.05). There were no significant changes in WOMAC-pain. Chemotaxis of neutrophils decreased significantly from 176 (113-204) to 138 (86-210) (p<0.05).

CONCLUSION:The present data suggest that Hyben Vital may slightly reduce osteoarthritic symptoms. A tendency towards a decline in the consumption of analgesics during treatment with Hyben Vital could explain the lack of effect on pain. The mode of action of Hyben Vital may include an anti-inflammatory effect.

