

# A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, CROSS-OVER TRIAL OF THE HERBAL REMEDY HYBENVITAL IN PATIENTS WITH OSTEOARTHRITIS

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## Introduction:

Alternative medicine is used extensively by patients with osteoarthritis (OA). 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 HybenVital, a standardised powder produced from seeds and shells of rose-hip (*Rosa Canina*).

HybenVital has been reported to inhibit certain leucocyte functions of potential relevance to inflammation.

## Methods:

Ninety patients with OA 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. Forty-five patients were given 5 HybenVital capsules 0.5 g twice daily, and 45 patients were given identical placebo capsules in the same dosage. After 3 months of treatment the group initially taking HybenVital was changed to placebo and vice versa.

Symptoms were scored by the WOMAC-questionnaire (VAS 0 – 100 mm), and calculated 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).

Patients were asked to record the consumption of analgesic medication throughout the two treatment periods.

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:

Fourteen patients left the study for reasons unrelated to study medication except for one patient who had difficulty in swallowing the capsules. Data are given for 76 patients who completed the study.

Baseline characteristics are given in Table 1, consumption of analgesic medication is given in Table 2, and WOMAC-scores are presented in Figure 1.

There were no adverse effects which could be related to HybenVital.

Chemotaxis of neutrophils decreased significantly from 176 (113 - 204) to 138 (86 - 210) ( $p < 0.05$ ).

## Table 1 Baseline characteristics (n =76)

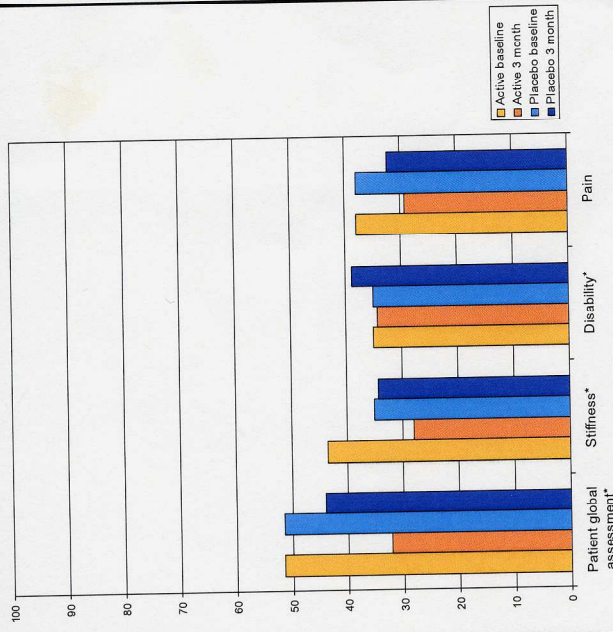
Age (years)	66 (35-89)
BMI (kg/m <sup>2</sup> )	26,2 (17,5-41,0)
Females/males (ratio)	2 : 1
Hip OA/knee OA (ratio)	3 : 4
Analgesic medication (%)	42

## Table 2 Analgesic medication (n=31)

	HybenVital	Placebo
Paracetamol (n=23)*	-3,5 (-1,0 - (-24,0))	4,0 (-6,0 - 9,0)
Weak opioids (n=8)*	-5,5 (-2,0 - (-19,0))	4,0 (0,0 - 16,0)

Data are given as the difference between the number of tablets taken per week in the beginning and at the end of the two treatment periods. \*  $p < 0.05$  for comparisons between treatment groups.

Figure 1 WOMAC-scores



\*  $p < 0.05$  for comparisons between treatment groups.

## Conclusion:

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