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A pollen extract (Cernilton) in patients with inflammatory chronic prostatitis-chronic pelvic pain syndrome: a multicentre, randomised, prospective, double-blind, placebo-controlled phase 3 study.

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Abstract

BACKGROUND:

National Institutes of Health (NIH) category III prostatitis/chronic pelvic pain syndrome (CP/CPPS) is a prevalent condition for which no standardised treatment exists.

OBJECTIVES:

To assess the safety and efficacy of a standardised pollen extract in men with inflammatory CP/CPPS.

DESIGN, SETTING, AND PARTICIPANTS:

We conducted a multicentre, prospective, randomised, double-blind, placebo-controlled phase 3 study comparing the pollen extract (Cernilton) to placebo in men with CP/CPPS (NIH IIIA) attending urologic centres.

INTERVENTION:

Participants were randomised to receive oral capsules of the pollen extract (two capsules q8h) or placebo for 12 wk.

MEASUREMENTS:

The primary endpoint of the study was symptomatic improvement in the pain domain of the NIH Chronic Prostatitis Symptom Index (NIH-CPSI). Participants were evaluated using the NIH-CPSI individual domains and total score, the number of leukocytes in post-prostatic massage urine (VB3), the International Prostate Symptom Score (IPSS), and the sexuality domain of a life satisfaction questionnaire at baseline and after 6 and 12 wk.

RESULTS AND LIMITATIONS:

In the intention-to-treat analysis, 139 men were randomly allocated to the pollen extract (n=70) or placebo (n=69). The individual domains pain (p=0.0086) and quality of life (QoL; p=0.0250) as well as the total NIH-CPSI score (p=0.0126) were significantly improved after 12 wk of treatment with pollen extract compared to placebo. Response, defined as a decrease of the NIH-CPSI total score by at least 25% or at least 6 points, was seen in the pollen extract versus placebo group in 70.6% and 50.0% (p=0.0141), respectively. Adverse events were minor in all patients studied.

CONCLUSIONS:

Compared to placebo, the pollen extract significantly improved total symptoms, pain, and QoL in patients with inflammatory CP/CPPS without severe side-effects.