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[Efficacy and safety profile of a herbal drug containing nasturtium herb and horseradish root in acute sinusitis, acute bronchitis and acute urinary tract infection in comparison with other treatments in the daily practice/results of a prospective cohort study]

[Article in German]
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Abstract

Patients and methods: In a prospective cohort study from 251 centers in Germany patients with age of 4 years or above who were treated due to acute sinusitis, bronchitis or urinary tract infections (UTI) in the period from 1st March 2004 - 30th July 2005, were elected. They were included in the study analysis, if they had no exclusion criteria (severe diseases, need for antibiotic therapy, participation in another trial) and came to the final investigation. The patients were treated either with the nasturtium herb and horseradish root containing herbal drug Angocin Anti-Infekt N (test group, n = 1223) or with standard antibiotic therapy (control group, n = 426). Treatment, dosage and treatment duration were determined by the physician in accordance with the patient. 536 subjects (408 test, 128 control patients) suffered from acute sinusitis, 634 subjects (469 test, 165 control patients) from acute bronchitis and 479 subjects (346 test, 133 control patients) from UTI. At study start and end the severity of the symptoms were judged by the investigator and quantified with 4 scores (0 = no symptom, 3 severe symptom). During the treatment information on use of medication, concomitant procedures and adverse events (AEs) in a patient diary. At the end of the study (disease free or after 7-14 days) the patient returned to the investigator, who recorded the vital parameters, finally judged the treatment efficacy and potential persisting symptoms on the basis of score values. Primary efficacy criterion was the change of the complaints quantified by the change of the relative symptom score averaged over all symptoms and related to the baseline value.

Results: In patients with acute sinusitis the mean relative reduction of the averaged symptom score was 81.3% for the test group and 84.6% for the control group, in patients with acute bronchitis the mean reduction was 78.3% for the test group and 80.3% for the control group, in patients with UTI 81.2% for the test group and 87.9% for the control group. The 95% confidence interval for the difference of the expected reductions between test and control group was -8.5% to 1.8% for acute sinusitis, 7.6% to 3.6% for acute bronchitis and -13.1% to -0.1% for UTI. Non-inferiority of the test

treatment, i.e. if the lower limit of the 95% confidence interval is greater than 10%, could be stated for acute sinusitis and bronchitis. In UTI the non-inferiority level was exceeded only by 3%. Complementary procedures were less in the test group than in the control group. For 1.5 % of test patients and 6.8% of control patients AEs were observed

Conclusion: Therapy with the herbal drug in the indications acute sinusitis, acute bronchitis und acute urinary tract infection is - with regard to its efficacy comparable to the treatment with standard antibiotics. The application of supportive procedures and the administration of concurrent medication were less expressed in the group treated with the herbal drug. In the above mentioned indications the group treated with the herbal drug displayed a clear advantageous safety profile compared to the group treated with standard antibiotics.

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