

Multi-symptom Relief and Improvement of Quality of Life - A Comparative Multicenter Trial on ColdZyme® Mouth Spray in Common Cold

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ABSTRACT

Introduction: ColdZyme® Mouth Spray (Enzymatica AB, Sweden) is a CE-marked medical device for protection against common cold. It consists of a barrier solution primarily containing glycerol, and trypsin obtained from the Atlantic cod. ColdZyme has been shown *in vitro* to completely inactivate up to 99 % of viruses causing common cold, among them influenza virus, rhinovirus, adenovirus, and corona virus.

Material & Methods. A prospective, multicenter, single (investigator)-blind, randomized study with parallel-group design, comparing ColdZyme to no treatment in 267 patients with naturally occurring common cold. Within 1 day from first symptoms, patients started using ColdZyme as two sprays 6 times daily until symptom free, and recorded parallel intake of symptom-relieving “rescue” medication (paracetamol, ibuprofen, or nose decongestants). Cold symptoms were assessed according to Jackson (1958) and quality of life by Wisconsin Upper Respiratory Symptom Survey (WURSS-21), Quality of Life (QoL) component (Barret 2009).

Results. There was no difference between the groups in symptom severity at study start. A significant effect on total symptom relief was seen in the active treatment group, with an AUC for total Jackson score of 39.6 ± 23.9 vs 46.2 ± 25.8 ($p=0.025$) over 7 days. ColdZyme treatment improved every single symptom, with significant effects seen on sore throat, nose congestion and headache. Active treatment also improved QoL from day one, with significant effects seen for all QoL parameters during the disease period (Table), and with a significant shortening of disease duration ($p = 0.030$).

WURSS-21 QoL single items, mean AUC ₁₋₇			
	Control	ColdZyme	p-value
Item 12: Think clearly	11.30	8.60	0.009
Item 13: Sleep well	17.48	14.66	0.039
Item 14: Breathe easily	18.14	14.88	0.018
Item 15: Walk, climb stairs, exercise	14.35	9.94	0.001
Item 16: Accomplish daily activities	13.24	9.82	0.007
Item 17: Work outside the home	13.72	9.74	0.003
Item 18: Work inside the home	12.66	9.07	0.006
Item 19: Interact with others	12.56	8.74	0.009
Item 20: Live your personal life	11.85	8.50	0.015

Table . Comparison of single items of the WURSS-21 QoL component during day 1-7

Number of subjects with use of symptom-relieving “rescue” medication throughout the first week was 23% lower in the ColdZyme group ($p=0.037$). No side effects attributable to ColdZyme were reported.

Conclusion: In this comparative multicenter trial, ColdZyme demonstrates an ability to reduce the overall severity of a common cold and to improve QoL significantly. The more frequent use of rescue medication in the control group indicates an even greater effect.