

## **REPORT ABOUT CLINICAL TRIAL WITH LYPRINOL® IN BRONCHIAL ASTHMA.**

The aim of this study was to assess efficacy and safety of Lyprinol in treatment of patients with bronchial asthma.

Forty patients (14 males and 26 female, aged 18-62 yrs, median age 40 yrs) with atopic steroid-naive asthma were enrolled in double-blind randomised placebo control study at the Hospital Therapeutic Clinic of Pavlov's Medical University, St-Petersburg, Russia. Thirty patients were treated with Lyprinol (2 capsules b.d.) during 8 weeks and ten patients were treated with placebo. Inhalations of  $\beta_2$ -agonists (salbutamol, fenoterol) were used by each group on demand. Patients were diagnosed according to the American Thoracic Society's definition of asthma. Diagnosis was based upon clinical history, reversibility of FEV<sub>1</sub> more than 15%. Their mean of duration asthma was 5,8±0,9yrs (mean±sem) and their mean FEV<sub>1</sub> at the time of the study was 86,3±3,3 % predicted mean±sem).

The study was approved by the Local Ethics Committee. The participants were informed and their consent was obtained in writing.

Pulmonary function tests included airway resistance, specific airway conductance "(Respiratory system 3000", Ohio Medical Products, Madison, USA), forced vital capacity, FEV<sub>1</sub>, mid-expiratory flow at 25, 50 and 75% of vital capacity ("Pneumoscreen II", Jaeger, Hoechberg, Germany). For assessment peak flow rate individual peak-flow meters were used (Vitalograph for Allersearch, Ireland). The concentrations of eosinophil cationic protein (ECP) were determined using radioimmunoassay (Pharmacia & Upjohn, Uppsala, Sweden). The concentration of hydrogen peroxide in exhaled air condensate were measured using horse radish peroxidase-catalysed oxidation of tetramethylbenzidine (Gallati & Pracht, 1985).

Student's paired two-tailed t-test was used for statistical methods (Microsoft Excel 5, Statistica for Windows 5). P value less than 0.05 was considered significant.

The results of the study are shown in tables 1 and 2. Lyprinol had positive effect on clinical symptoms, peak expiratory flow (PEF) rate and concentration of hydrogen peroxide in exhaled air condensate. there were no improvement in placebo treated group. No side effects were observed in both groups of asthmatic patients during the treatment with Lyprinol® or placebo.

In conclusion, this study has revealed some beneficial effects of Lyprinol® in mild asthmatic patients. These findings provide evidence that Lyprinol® may have antiinflammatory activity on airways. Further studies are needed to assess efficacy and safety of Lyprinol® in patients with moderate asthma.

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Table 1. Efficacy of Lyprinol® in patients with bronchial asthma.

	Baseline	28 days	56 days
Chest tightness (times/day)	1,57±0,29	0,89±0,18*	1,0±0,42*
Night awakeness (times/day)	0,54±0,12	0,25±0,10*	0,16±0,09*
Usage of $\beta$ 2-agonists (puffs/day)	1,61±0,44	0,77±0,30*	0,87±0,35*
FEV1 (% predicted)	80,29±3,91	71,96±3,77	81,29±3,86
PEF (l/min)	360,35±15,52	366,07±18,51	398,75±18,32*
Hydrogen peroxide in breath air condensate ( $\mu$ M)	0,135±0,025	0,086±0,014*	0,058±0,009*
ECP in serum ( $\mu$ g/l)	6,57±1,22	8,03±2,26	5,77±0,87 (n=17)

Values are presented as mean±sem. \* p<0.05 versus baseline

Table 2. Clinical symptoms, lung function tests and makers of airway inflammation in asthmatic patients treated with placebo.

	Baseline	28 days	56 days
Chest tightness (times/day)	1,0±0,30	0,81±0,32	0,87±0,19
Night awakeness (times/day)	0,1±0,08	0,16±0,11	0,18±0,12
β2-agonists (puffs/day)	0,08±0,08	0,16±0,16	0,27±0,27
FEV1 (% predicted)	100,18±3,6	83,6±3,0	101,49±2,88
PEF (l/min)	461,66±26,82	447,27±40,23	465,45±37,84
Hydrogen peroxide in breath air condensate (μM)	0,21±0,12	0,14±0,50	0,09±0,20
ECP in serum (μg/l)	6,19±1,02	4,82±0,92	7,42±1,84

Values are presented as mean±sem. \* p<0.05 versus baseline