Effects of Human Placenta Extract Laennec on Quality of Life and Physical Performance in Patients with Chronic Fatigue Syndrome

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potentiating the restoration of the body's adaptive resources, in

frst decade of the 20th century, after discovering new technics for placenta's extracts and suspensions preparation (Gromova

f patients with verifed diagnosis "Chronic fatigue syndrome" (CFS). ***Material and methods:*** *The study patients with CFS, randomized into 2 groups: the experimental group (HPEL, 24 people) - patients d by 10 intravenous Laennec infusions, 4 ml each, 2 times/week, for 5 weeks and passive control group pers.). Before, after, and 5 weeks follow-up treatment efcacy was evaluated by severity of chronic ronic Fatigue inventory), state anxiety and depression level (STAI and STDI) and Health related Quality QoL, questionnaire SF-36v2), exercise tolerance (cardiopulmonary exercise test with gas analysis), meters.* ***Results:*** *The HPEL patients showed a signifcant reduction in index of chronic fatigue values, accompanied by signifcant decrease in situational depression, anxiety, improvements in subjective*

fatigue was not verifed as CFS, improvement of fatigue was signifcantly higher in CTRL group.

the effcacy and safety of HPE Laennec intravenous infusions in treatment of patients with verifed diagnosis of CFS.

METHODS

Participants and Randomisation

HPE Laennec Infusion Program

Registering certifcate No. 013851/01-08, Ministry of Health,

collected patients' reports on possible side effects and adverse

Evaluation of Psychological Status and Functional Exercise Capacity

and liver, infammatory parameters), consulting by neurologist to

38 patients with verifed diagnosis of CFS (G 93.3), 18 men and 20

Table 1. No statistically signifcant differences occurred between

by the certifed biochemical laboratory (NPO "Efs", Moscow)

Table 1.
Demographic information and characteristics of the subjects

Demographic and clinical information	**HPEL(n=23)**	**CTRL(n=13)**	**P value**
Sex:Male – n (%)	10 (43.5%)	7 (53%)	ns
Age, years	45.4 (30. 61)	44 (28.62)	ns
Smoking – n (%)	4 (17.4%)	3 (23%)	ns
Height, cm	171.4 (158-190)	172.9 (156-178)	ns
Weight, kg	75 (60-102)	75 (60-102)	ns
Comorbidities and medication			
Arterial Hypertension – n (%)	5 (21.7%)	2 (15.4%)	ns
Hypotensive therapy– n (%)	5 (21.7%)	2 (15.4%)	ns
Diabetes Mellitus T2 – n (%)	1 (4.3%)	-	ns
Hypoglicaemic therapy	1 (4.3%)	-	ns
Decreased VO2 peak (<84% predicted individual values), ml/kg/min	16 (69.6%)	6 (46.2%)	0.032

scores were computed by frst transforming and summarized in an

36 Health Survey. The 36 items refect the eight scales: physical

scale is computed by frst transforming the raw scores into a range

The subjects' improvement in exercise tolerance was checked by Cardiopulmonary stress test (Fitmate MED (COSMED, Italy)

-4,6 -7,5 -10,0 METs. Peak oxygen uptake (VO

higher than at the baseline. CTRLs showed no signi f cant change

Functional Exercise Capacity

AT, the total exercise time to exertion and other parameters of

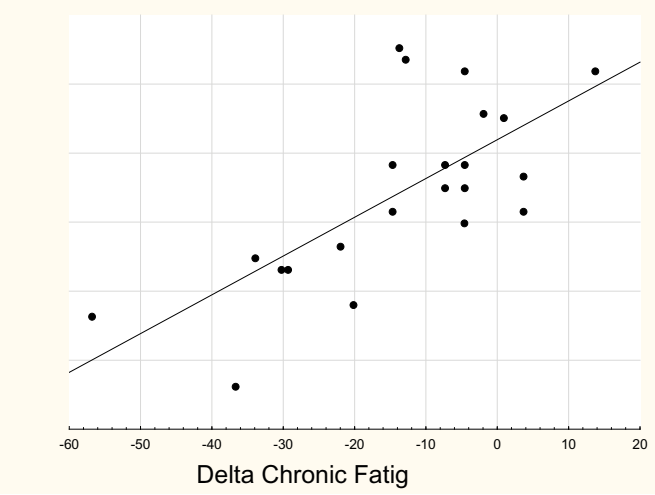
no signi f cant difference. After the treatments HPEL group showed

peak, which were signi f cantly high than

statistic signi f cant difference between the groups in time to reach AT (Table 3). SBP max at the maximum

signi f cantly, but not in CTRL.

6	**% VO_2 peak**	HPEL	78.4 ± 17.4	87.2 ± 17.2*#	85.9 ± 16.9*
		CTRL	85.2 ± 14.6	77.5 ± 10.1	-
7	**VO2AT, ml/kg/min**	HPEL	17.3 ± 3.6	19.9 ± 4.3*	20.4 ± 4.9*
		CTRL	21.8 ± 2.8	19.5 ± 2.4	-
8	**% VO_2AT**	HPEL	66.4 ± 5.3	70.1 ± 5.9*#	71.6 ± 5.1*.**
		CTRL	72.8 ± 9.5	64.5 ± 9.9	-
9	**SBP max, mmHg**	HPEL	162.5 ± 17.4	145.8 ± 16.3*#	142.6 ± 9.0*
		CTRL	157.1 ± 11.8	160.5 ± 14.9	-
10	**DBP max, mmHg**	HPEL	87.2 ± 8.5	83.7 ± 5.7	92.3 ± 6.1**
		CTRL	98.1 ± 8.1	96.6 ± 8.3	-



We discovered a high significant negative relationship between inter-individual variability recorded parameters and confirm the absence of specific laboratory indicators of immune response and significant positive relationship between the differences of the CFI

There were no significant changes in the immune, hormonal

only in cholesterol metabolism (a signi f cant reduction in total cholesterol from 5.76 ± 1.18 to 4.83 ± 1.07 Mmol/L, p ≤ 0.042 and LDL cholesterol from 3.55 ± 1.18 to 2.93 ± 0.99 Mmol L p ≤ 0.039), that con f rms hepatoprotective and normalizing lipid metabolism

DISCUSSION

condition. Aside from the adverse effects to patients' health,

We found statistically signi f cant relevant improvements in

of individual strength (CIS), based on subjects' self-reports, and fatigue was not veri f ed by neurologist as CFS.

HRQoL subscales in sample group with veri f ed primary diagnosis

in different patients' categories (Spielberg et al., 2004). In CFS subjects HPE infusions reduce fatigue, potentiate physical f tness

To our knowledge this is the f rst study that investigated the effects of HPE Laennec intravenous infusions on CFS patients'

parameters. We observed signi f cant increase in HPEL subjects'

signi f cantly in CTRL.

period of time. In concordance to Kong et al., who did not f nd

Multiple positive effects of Laennec infusion on CFS