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Clinical efficiency of treatment painful diabetic polyneuropathy with different treatment regimes of alpha-lipoic acid

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The main aim of the study was to evaluate the clinical efficiency and safety of different regimes of oral therapy with alpha-lipoic acid (ALA) in painful diabetic polyneuropathy (PDPN). The additional goals are the following: analysis of the groups of responders and non-responders, recurrence of pain symptoms rates and evaluation of the effectiveness of ALA therapy depending on the HbA1c levels. Methods: The study is a prospective open randomized comparative clinical trial in 4 parallel groups. The research involved the patients with diabetes mellitus with previously diagnosed of PDPN and the pain on VAS> 40 mm, the rate of TSS> 7,5 points. The patients were random-ized into 4 parallel groups: Group 1 (n-31) received 600 mg of ALA once a day, Group 2 (n-28) - 300 mg b.d., Group 3 (n-35) – 900 mg once a day and group 4 (n-27) – 300 mg 3 times a day). Active treatment period was 3 months, observation period - 1 year. The results: The efficiency of different regimes of ALA prescription in PDPN (600x1t.d.; 300x2t.d.; 900x1t.d.;300x3t.d.;) by the TSS, VAS, NIS LL and NIS LL-sens. scores were similar. ALA intake 300 mg 3 t. d. was characterized significant decreasing of neuro-logical symptoms on a scale of NTSS-6 and -9 compared with the dose of 600 mg once or 300 mg 2 times. Moreover, the dynamic of NTSS-6 and -9 scale were higher in patients with 300mg x 3 times intake than 900 mg intake once, but this value was not significant ($p \geq 0,05$). We analyzed the responders (n=86) and non-responders (n=29) subpopu-lations. The predictors of the efficiency of ALA treatment are the HbA1c-level and sensor deficiency. The moderate correlation is observed between HbA1c level (>8%), NIS LL and NIS LL-sensor function scores and frequency of the answer on ALA treatment (R Spearman – 0,251; p-0,007 // r–0,32; p-0,00077 // r-0,31; p-0,0015 respectively). The frequency of pain recurrence were not depend on previous dosing regimes of ALA, but was determined by the initial level of HbA1c («no-relapse» 7,38±1,05 vs. «relapse» 8,05±0,9; p=0,013). The patients who had level of HbA1c <of 7,0 %, were characterized the maximum dynamics of NTSS-6, NTSS-9, NIS LL and NIS LL-sensor function scores . Conclusions: ALA intake (300mg 3 times daily) was associated with relevant decreasing the NTSS-6 and NTSS-9 scores. The frequency of pain recurrence were not depend on previous dosing regimes of ALA, but was determined by the initial level of HbA1c . The high level of HbA1c (>8,0%), negative monofilament test may be predictors of low ALA treatment efficiency.