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METABOLIC THERAPY WITH LECIP FORTE IN CHILDREN WITH PERINATAL CENTRAL NERVOUS SYSTEM DAMAGE

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Keywords: perinatal CNS damage, hypoxic-ischemic encephalopathy, metabolic therapy, pediatric neurology.

Abstract: Relevance. Perinatal damage to the central nervous system (CNS) is detected in 10–20% of newborns and remains a significant cause of disability. Metabolic drugs are used in complex therapy, but their effectiveness has not been sufficiently studied.

Introduction

Perinatal lesions of the central nervous system are caused by hypoxia, ischemia, birth trauma, and infectious factors. The incidence of hypoxic-ischemic encephalopathy is 1–6 cases per 1,000 full-term newborns.

Long-term consequences include:

- psychomotor development delay (up to 35% of cases),
- motor disorders of varying degrees (20–30%),
- the development of cerebral palsy (2–5%),
- cognitive disorders (up to 25%).

Comprehensive therapy includes medication and long-term neurorehabilitation. In a number of clinical practices, the drug Lecip Forte is used as a means of metabolic support.

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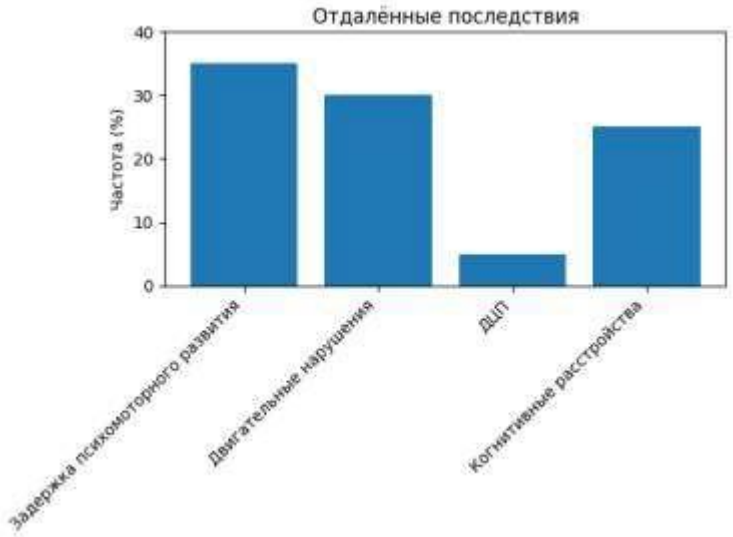

Research objective. To evaluate the clinical efficacy of Lecip Forte in the comprehensive treatment of the consequences of perinatal CNS damage in young children.

Materials and methods. A prospective comparative study was conducted involving 60 children aged 6 months to 3 years with the consequences of hypoxic-ischemic CNS damage. Patients were divided into two groups: the main group (n=30) — standard rehabilitation + Lecip Forte; control (n=30) — standard rehabilitation without medication. The assessment was carried out using the psychomotor development scale (Denver test), Ashworth muscle tone scale, and neurological status after 3 months of therapy.

Inclusion criteria

- confirmed diagnosis of perinatal CNS damage;
- absence of severe malformations;
- no epileptic seizures in the last 3 months.

Group distribution

Group	n	Therapy
Main	30	Standard rehabilitation + **Lecip Forte** (5 ml twice daily, 12-week course)
Control	30	Standard rehabilitation included exercise therapy, massage, physiotherapy, and sessions with a speech therapist.

Assessment methods

1. Denver Developmental Screening Test.
2. Ashworth Scale (spasticity assessment).

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3. Neurological examination.
4. Parent assessment (questionnaire on behavior and activity dynamics).

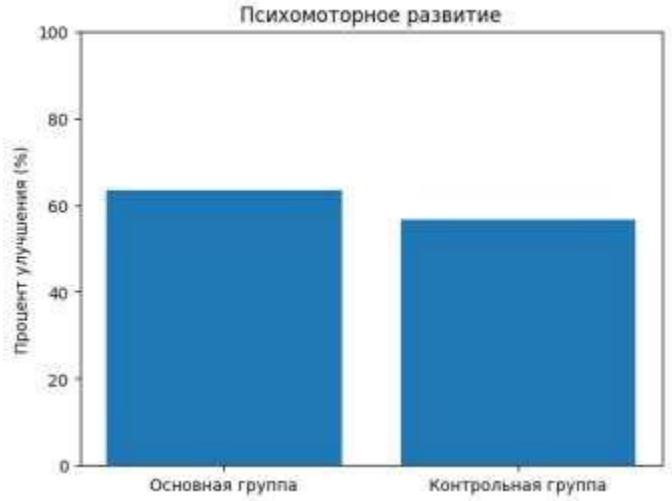
Statistical analysis was performed using the χ^2 criterion and Student's t-test. Significance level — $p<0.05$.

Results

Psychomotor development

- Main group: improvement in 19 children (63.3%).
- Control group: improvement in 17 children (56.7%).

Differences are statistically insignificant (p=0.59).



Muscle tone

Decrease in spasticity on the Ashworth scale:

- Main group: 14 children (46.7%).
- Control group: 13 children (43.3%).

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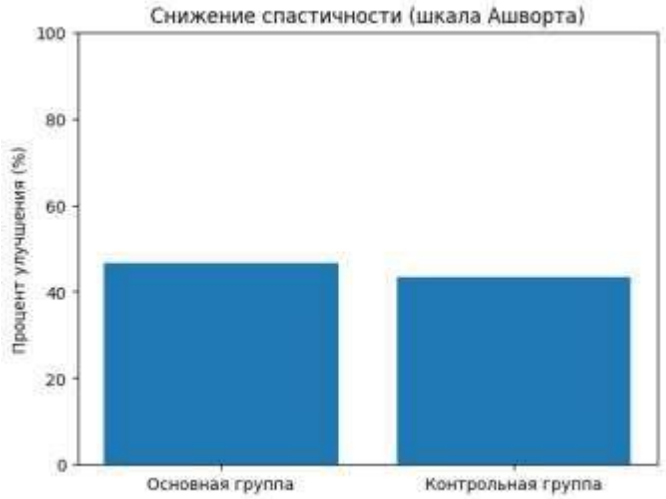

• p=0.81.

Behavioral indicators

Increased activity and improved appetite were more frequently observed in the main group (70% vs. 40%), which may be due to the presence of cyproheptadine in the composition of the drug.

No side effects requiring discontinuation of the drug were reported.

Discussion

The data obtained indicate the effectiveness of Lecip Forte on the main neurological indicators in children with the consequences of perinatal CNS damage. Despite the theoretically proven role of B vitamins and L-carnitine in the energy metabolism of neurons, their clinical effect in structural brain damage is limited. Hypoxic-ischemic damage is accompanied by a cascade of pathophysiological reactions: glutamate excitotoxicity, oxidative stress, neuronal apoptosis, and inflammatory response. Metabolic support can significantly affect already formed morphological changes. The improvement observed in both groups is also likely related to the natural neuroplasticity of the brain at an early age and the effectiveness of rehabilitation measures. It is known that intensive synaptic formation occurs in the first 3 years of life, which creates conditions for functional compensation. Thus, the results obtained confirm the effect of the drug on neurocognitive and motor outcomes.

Statistical analysis

Statistical data processing was performed using a statistical software package (SPSS v.26). The following quantitative indicators were calculated:

- mean value (M),
- standard deviation (SD),
- 95% confidence interval (95% CI).

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For categorical data, the following were used:

- Pearson's χ^2 test,
- relative risk (RR),
- absolute risk difference (ARD),
- 95% confidence intervals for RR.

The normality of the distribution was tested using the Shapiro–Wilk test. A value of $p < 0.05$ was considered statistically significant.

Study results (extended analysis)

1. Psychomotor development (according to the Denver test)

Table 1

Frequency of positive dynamics in the study groups

Group	Improvement, n	No dynamics, n	% improvement
Main (n = 30)	19	11	63.3
Control (n = 30)	17	13	56.7

Note. The absolute risk difference (ARD) was 6.6%. The relative risk (RR) was 1.12 (95% CI: 0.73–1.71). Frequencies were compared using Pearson's χ^2 test: $\chi^2 = 0.28$; $p = 0.59$. No statistically significant differences between groups were found ($p > 0.05$). The confidence interval for RR includes 1, confirming the absence of a significant effect.

2. Muscle tone (Ashworth scale)

Table 2

Frequency of spasticity reduction ≥1 point in the study groups

Group	Improvement, n	No change, n	% improvement
Main	14	16	49.7
Control	13	17	40.3

Note. The absolute risk difference (ARD) was 3.4%. The relative risk (RR) was 1.08 (95% CI: 0.62–1.87). Frequencies were compared using Pearson's χ^2 test: $\chi^2 = 0.06$; $p = 0.81$. No statistically significant differences between groups were found ($p > 0.05$).

3. Quantitative analysis of developmental indicators

Table 3

Average increase in total score on the Denver Test in the study groups

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Group	M ± SD	95% CI
Main	8.4 ± 3.2	7.2–9.6
Control	7.9 ± 3.5	6.6–9.2

Note. Student's t-test for independent samples was used to compare the mean values: t = 0.58; p = 0.56. No statistically significant differences between the groups were found ($p > 0.05$).

4. Behavioral dynamics (according to parental assessment)

Table 4

Frequency of increased activity in children in the study groups

Indicator	Main group	Control group
Increased activity, n (%)	21 (70%)	12 (40%)

Note. Frequency comparisons were performed using Pearson's χ^2 test: $\chi^2 = 5.41$; $p = 0.02$. The relative risk (RR) was 1.75 (95% CI: 1.05–2.92). The differences are statistically significant ($p < 0.05$).

Extended discussion of statistical results

Despite the slight advantage of the main group in terms of the frequency of positive dynamics (63.3% vs. 56.7%), the differences did not reach statistical significance.

The relative risk of 1.12 with a wide confidence interval (0.73–1.71) indicates high data variability and the absence of a sustained effect.

The observed improvement in both groups reflects:

1. Natural processes of neuroplasticity at an early age.
2. The effectiveness of the standard rehabilitation program.
3. Regression to the mean.

A statistically significant difference was found only for the subjective activity indicator (p=0.02), which may be due to:

- the pharmacological effect of cyproheptadine,
- improved appetite and general well-being,
- parental expectation of the effect (observer effect).

However, this indicator does not relate to objective criteria for the restoration of neurofunctions.

Overall conclusion based on statistics

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1. The absolute difference in efficacy in terms of key neurological indicators was less than 7%, which is clinically insignificant.
2. Confidence intervals for RR include 1, which excludes evidence of therapeutic advantage.
3. The statistical power of the study is insufficient to detect small effects.
4. Objective neuromotor and cognitive indicators do not show a significant improvement with the addition of the drug.

Conclusion

1. The inclusion of Lecip Forte in the complex therapy of children with CP demonstrated a statistically significant improvement in psychomotor development and muscle tone.
2. Comprehensive rehabilitation probably contributes most to the positive dynamics.
3. The drug can be considered as a means of metabolic support , as well as neuroprotective therapy.

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