Minimal essential text

(Key findings + graphics)

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The Effect of Levocarnitine on Dynamics of the Brain Bioelectrical Activity Formation in Term Infants Delivered by Cesarean Section: Open Randomized Trial Results

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Background*. The brain activity of a newborn affects postnatal adaptation, the disorder of which can cause dysfunction of organs and systems of the immature organism and the development of diseases in more distant periods of maturation.* ***Objective:*** *Our aim was to study the effect of levocarnitine on dynamics of the brain bioelectrical activity formation in term infants delivered by cesarean section.* ***Methods.*** *The study included term infants (gestation period 38–40 weeks) delivered by cesarean section, with perinatal hypoxic lesion of the central nervous system (cerebral ischemia). Children were randomized into groups of standard (recommended) treatment and standard treatment enhanced with levocarnitine (plus levocarnitine) — 30% oral solution at a dose of 100 mg/kg per day for 3 weeks starting from the 7th day of life. The brain bioelectrical activity was assessed with electroencephalography (EEG) of the natural sleep period on the 3rd-6th day and then at 3, 6, and 12 months.* ***Results.*** *45 children were randomized into groups of standard treatment and standard treatment plus levocarnitine, of which 44 and 40 children completed the study, respectively. Initially, the delayed formation of age-related brain activity was detected in 16/40 (40%) children receiving levocarnitine and in 19/44 (43%) in the experimental group (p = 0.767), disturbances in the EEG sleep pattern with generation of background anomalies — in 17 (43%) and 16 (36%) (p = 0.565), pathological graph elements — in 1 (3%) and 2 (5%) children (p = 0.536), respectively. According to the dynamic EEG control results, it was found that after 1 year the cerebral dysfunction was registered less frequently in children receiving levocarnitine — in 32 (80%) vs. 42 (96%) children in the group of standard treatment (p = 0.028).* ***Conclusion.*** *Adminisration of levocarnitine in the neonatal period reduces the risk of developing cerebral dysfunction by the end of the first year of life.*
Key words: *newborns, cesarean section, cerebral ischemia, electroencephalography, sleep disorders, levocarnitine.*
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RESULTS

Table 1. Brief characteristics of the children included in the study

Indicator	Levocarnitine, *n* =40	Standard treatment, *n* =44	*p*
Girls, abs. (%)	20 (50)	16 (36)	0.207
Birth weight, g	3250 ± 750	3180 ± 566	0.632
APGAR score, points			
• 1st minute	7.3 ± 1.2	7.2 ± 1.3	0.779
• 5th minute	7.4 ± 1.2	7.4 ± 1.2	0.814
Neurological syndromes, abs. (%)			
• Excitement	22 (55)	25 (57)	0.866
• Depression	15 (38)	17 (39)	0.914
• Convulsions	2 (5)	2 (5)	0.922
• Vegetative-visceral	23 (58)	24 (55)	0.785
Severity of cerebral ischemia, abs. (%)	18 (45)	22 (50)	0.646
• Mild	18 (45)	16 (36)	0.420
• Medium	4 (10)	6 (14)	0.607
• Severe			
INFANIB score, points	48.1 ± 17.6	48.4 ± 13.5	0.935
• Normal, abs. (%)	7 (18)	8 (18)	0.935
• Transient disorder, abs. (%)	25 (63)	28 (64)	0.914
• Pathology, abs. (%)	8 (20)	8 (18)	0.832
Sleep EEG pattern, abs. (%)			
• Type I	7 (18)	9 (20)	0.730
• Type II	16 (40)	19 (43)	0.767
• Type III	14 (35)	13 (30)	0.592
• Type IV	2 (5)	3 (7)	0.725
• Type V	1 (3)	0	0.476
Standard treatment, abs. (%)			
• Resuscitation	11 (28)	13 (30)	0.835
• Respiratory support	12 (30)	14 (32)	0.857
• Tube feeding	8 (20)	10 (23)	0.760

Table 2. Cerebral dysfunction in children in the compared groups during the first year of life

Groups	Age periods, months			
	3-6 days	3	6	12
Levocarnitine, *n* = 40	33 (83)	33 (83)	36 (90)	32 (80)
Standard treatment, *n* = 44	35 (80)	38 (86)	41 (93)	42 (95)
p	0.730	0.624	0.598	0.028

Table 3. Dynamics of the main neurological symptomatology in children who received standard treatment (*n* = 44) and standard treatment plus levocarnitine (*n* = 40)

Indicator	1-3 days		*p*	1 month		*p*	1 year		*p*
	Levocar-nitine	Standard treatment		Levocar-nitine	Standard treatment		Levocar-nitine	Standard treatment	
Excitement	22 (55)	25 (57)	0.866	28 (70)	34 (77)	0.449	6 (15)	13 (30)	0.111
Depression	15 (38)	17 (39)	0.914	2 (5)	2 (5)	0.960	0	0	-
Convulsions	2 (5)	2 (5)	0.922	2 (5)	2 (5)	0.922	1 (3)	1 (2)	0.945
Vegetative dysfunction	23 (58)	24 (55)	0.785	12 (30)	16 (36)	0.536	6 (15)	5 (11)	0.621
Muscle tone disorders	33 (83)	32 (73)	0.285	30 (75)	30 (68)	0.489	13 (33)	15 (34)	0.817
Delay in	-	-	-	13 (33)	16 (36)	0.709	3 (8)	4 (9)	0.792

psychomotor development									
Hypertensive syndrome	-	-	-	1 (3)	2 (5)	0.613	1 (3)	2 (5)	0.613
Febrile convulsions	-	-	-	-	-	-	1 (3)	1 (2)	0.945
Sleep disorders	-	-	-	-	-	-	6 (15)	16 (36)	0.026

FINANCING SOURCE
Not specified.

CONFLICT OF INTERESTS
Not declared.

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