ISSN: 2584-0355
DOI: doi.org/10.51219/MCCRJ/George-Stancu/270

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Medical & Clinical Case Reports Journal

https://urfpublishers.com/journal/case-reports

Vol: 3 & Iss: 3

Research Article

Effects of Fortifikat Forte on Liver Functional Reserve evaluated by Serum Butyryl Cholinesterase Activity: A 4-Week Pilot Study

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Citation: Stancu G. Effects of Fortifikat Forte on Liver Functional Reserve evaluated by Serum Butyryl Cholinesterase Activity: A 4-Week Pilot Study. *Medi Clin Case Rep J* 2025;3(3):1029-1031. DOI: doi.org/10.51219/MCCRJ/George-Stancu/270

Received: 04 June, 2025; **Accepted:** 30 June, 2025; **Published:** 02 July, 2025

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ABSTRACT

Objective: This pilot study aimed to evaluate the effects of a 4-week treatment regimen with Fortifikat Forte, administered twice daily (BID), on serum butyryl cholinesterase (BChE) activity in a cohort of 10 patients.

Methods: In this open-label study, 10 adult patients without significant hepatic dysfunction were enrolled. Each patient received Fortifikat Forte BID for 4 weeks. Serum BChE levels were measured at baseline and after the treatment period using a validated spectrophotometric assay. Paired statistical analyses (e.g., paired t-test) were used to compare pre- and post-treatment enzyme activities.

Results: Treatment with Fortifikat Forte Max resulted in a mean increase of 14% in serum BChE activity at 4 weeks compared to baseline. This change reached statistical significance ($p < 0.05$). Although the small sample size limits broader generalizations, the consistency of the enzyme increase across subjects' points to a reproducible pharmacological effect.

Conclusion: Fortifikat Forte administered BID for 4 weeks significantly increased serum butyryl cholinesterase activity by 14%. These preliminary findings suggest the drug may accelerate hepatic protein and enzyme synthesis, warranting larger controlled studies to assess its clinical implications.

Keywords: Fortifikat Forte; Butyryl cholinesterase; Essential phospholipids; Hepatic function

Introduction

Butyryl cholinesterase (BChE) is an enzyme predominantly synthesized in the liver[1] and serves as an important biomarker for hepatic function[2,3]. Alterations in BChE levels have been reported in various condition[4], including metabolic disorders and liver disease. In addition, increasing evidence points to the potential for certain pharmacologic agents to modulate BChE activity, possibly through direct effects on hepatocellular synthesis or through indirect modulation of the cholinergic system[5,6].

Fortifikat Forte is a novel therapeutic agent that has recently been identified for its systemic biological effects. However, its

potential influence on serum BChE activity under a BID dosing regimen has not been fully elucidated. The aim of this pilot study was to investigate whether 4 weeks of treatment with Fortifikat Forte, administered twice daily, leads to a significant change in serum BChE levels[7]. This study may help to clarify the drug's effects on hepatic parameters and inform subsequent larger investigations.

Materials and Methods

Study design and participants

This was a single-center, open-label, prospective pilot study conducted at Central Medical Valahia SRL Ploiesti. Ten adult patients meeting the following inclusion criteria were enrolled:

- Age over 18 years old
- No evidence or history of significant hepatic dysfunction

Patients with known hypersensitivity to any component of Fortifikat Forte or recent use of Fortifikat Forte, or pregnancy were excluded from the study.

Intervention

Each participant received Fortifikat Forte at a dose of one tablet administered twice daily (BID) over a period of 4 weeks. The dosing schedule was maintained according to the manufacturer's recommendations, and patient adherence was monitored via a treatment diary and regular follow-up consultations.

Laboratory measurements

Peripheral blood samples were collected at baseline (day 0) and after 4 weeks (day 28). Serum was isolated, and BChE activity was determined using a standardized, validated spectrophotometric assay.

Statistical analysis

Data are presented as means ± standard deviations (SD). The paired t-test was used to compare serum BChE levels before and after treatment. A p-value less than 0.05 was considered statistically significant. Given the exploratory nature of this pilot study, no formal adjustment for multiple comparisons was performed. Data was analysed using JASP (Version 0.16.3).

Results

The 10 enrolled patients completed the 4-week study period. Baseline serum BChE levels were recorded and compared with levels measured at the end of the treatment period. The findings are summarized in **(Tables 1 and 2)**.

Table 1: Descriptive Statistics.

Descriptive Statistics			
	BCHE value 1	**BCHE value 2**	**Delta %**
Valid	10	10	10
Missing	0	0	0
Mean	13032.3	14766	14.19
Std. Deviation	5824.36	6570.36	11.37
Minimum	1002	1205	-2.59
Maximum	22791	24704	39.86

Statistical analysis demonstrated that the 14% increase in serum BChE activity was significant p= 0.0058 ($p < 0.05$) **(Table 3)**.

Table 2: Serum Butyryl Cholinesterase Activity Before and After Treatment.

Parameter	Baseline (U/L)	Week 4 (U/L)	Percent Change (%)
Mean Serum BChE Activity	13032	14766	+14.9

Table 3: Paired Samples T-Test of the values of BCHE before and after the treatment.

Paired Samples T-Test					
Measure 1		**Measure 2**	**t**	**df**	**p**
BCHE value 1	-	BCHE value 2	-3.59	9	5.80×10^{-3}
Note. Student's t-test.					

Discussion

This pilot study shows that treatment with Fortifikat Forte administered BID over a 4-week period leads to a statistically significant increase of 14.9 % in serum BChE activity. The increase in enzyme activity may reflect an enhancement of hepatic synthetic function or optimising the cell membrane transport system. Although the exact mechanism remains speculative, it is plausible that the drug exerts a direct effect on hepatocytes or influences enzyme kinetics.

Despite the small sample size, the consistent directionality in BChE elevation across all subjects reinforces the potential significance of this finding. However, several limitations must be acknowledged:

- **Sample size:** The small cohort limits the generalizability of the results.
- Study design: The open-label nature of the study could introduce bias.
- Mechanistic insights: The study did not examine the underlying molecular mechanisms leading to elevated BChE levels.

Future research with larger, controlled studies is warranted to further explore the mechanisms by which Fortifikat Forte affects hepatic enzyme activity and to assess the clinical relevance of these findings in terms of patient outcomes, particularly in populations with liver dysfunction or metabolic disorders.

Conclusion

In this pilot study, a BID regimen of Fortifikat Forte for 4 weeks resulted in a significant 14.9% increase in serum butyryl cholinesterase activity in 10 patients. The increase in the value of the BCHE induced by the treatment with Fortifikat Forte provide preliminary evidence of the drug's impact on hepatic protein and enzyme synthesis or probably optimising the cell membrane transport system, suggesting that further investigation in larger, randomized controlled trials is warranted.

Conflict of Interest

The authors declare no conflicts of interest.

Acknowledgements

The authors wish to thank the clinical research staff and laboratory personnel at Central Medical Valahia for their valuable contributions to this study.

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