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## Effect of vitamin B6 supplementation, in combination with magnesium, on severe stress and magnesium status: secondary analysis from an RCT

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### Abstract

**Introduction:** Evidence from a recent randomised controlled trial<sup>1</sup> suggests that in severely stressed subjects with low magnesemia, supplementation with magnesium (Mg) in combination with vitamin B6 (B6) provides greater benefits than Mg alone. B6 was reported to facilitate Mg absorption and its cellular uptake and to exert synergistic effect with Mg. The current secondary analysis explored the relationship between Mg-B6 combination and erythrocyte Mg concentration, used as a biomarker of body Mg status.

**Material and Methods:** An 8-week, Phase IV, controlled, single-blinded, parallel-group trial (EudraCT Number 2015-003749-24) stratified by sex was conducted in adults (n = 264) with a Depression Anxiety Stress Scales - stress subscale score (DASS-42SS) > 18 and serum Mg of 0.5–0.85mmol/L, randomised 1:1 to daily oral Mg-B6 (Magne B6®, Mg 300mg; B6 30mg) or oral Mg alone (Magnespasmyl®, Mg 300mg). Outcomes were stress score, serum Mg (mmol/L), erythrocytes Mg (mmol/L), and serum B6 (nmol/L) from baseline to Week4 and Week8. Data are given as mean(SD) values.

**Results & Discussion:** Baseline characteristics. Baseline magnesemia was 0.80(0.04) for both groups. Erythrocyte Mg concentration for the lower quintile of the studied population (n = 53) was 0.73–1.62, below the normal range of 1.65–2.65 in general population. The mean stress score in this subgroup was higher [29.5(6.3)], but not significantly different from that in other quintiles [lowest value: 26.1(7.6)]. Baseline B6 serum level for the lower B6 quintile (5–23), below the normal range for general population, was suggestive of possible B6 deficiency.

**Treatment effects.** Both treatments increased slightly but not significantly erythrocyte Mg level from baseline to Week8 [1.84(0.03) to 1.86(0.03), and 1.86(0.03) to 1.88(0.03), respectively for Mg + B6 and Mg groups]. Significant changes were observed in subjects with low erythrocyte Mg level at baseline (<1.6), namely an increase of +0.13(0.04–0.22) for Mg + B6 and +0.17(0.08–0.25) for Mg groups, but with no difference between treatments. Moreover, Mg + B6 supplementation led to a significant change (p < 0.0001) in serum B6 level between baseline and Wk8 [55.9(4.8) to 370.9(11.3)], as compared to Mg alone [51.9(4.8) to 51.5(11.3)].

In conclusion, both treatments significantly increased erythrocyte Mg in subjects with low Mg status. B6 supplementation did not lead to further increase in erythrocyte Mg level. We have previously shown that severely stressed population benefits from B6 supplementation in combination with Mg, however, the mechanism of the interaction between Mg and B6 remains to be elucidated.

<sup>1</sup>Sponsored by Sanofi

### Conflict of Interest

Lionel Noah and Etienne Pouteau belong to the medical department, at CHC sanofi company.