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A RANDOMISED CONTROLLED TRIAL ON THE EFFECT OF B-VITAMINS ON NEURONAL INJURY IN PLHIV

Erika Ahlgren[1], Lars Hagberg[1], Lars-Magnus Andersson[1], Aylin Yilmaz[1], Åsa Mellgren[1] , Kaj Blennow[2], Henrik Zetterberg[2], Magnus Gisslén[1]

1 Institute of Biomedicine, Department of Infectious Diseases, the Sahlgrenska Academy at the University of Gothenburg, Gothenburg, Sweden. 2 Institute of Neuroscience and Physiology, Department of Psychiatry and Neurochemistry, the Sahlgrenska Academy at the University of Gothenburg, Gothenburg, Sweden.

CONCLUSIONS

- P-HOMOCYSTEINE AND P-NFL LEVELS CORRELATE IN NEUROASYMPTOMATIC PLHIV ON ART.
- B-VITAMIN SUBSTITUTION DECREASED HOMOCYSTEINE.
- NO EFFECT ON P-NFL AFTER 12 MONTHS OF SUBSTITUTION SUGGESTING A NON-CAUSAL ASSOCIATION BETWEEN HOMOCYSTEINE AND NEURONAL INJURY IN PLHIV.

Background

We have previously found an association between plasma homocysteine levels and cerebrospinal fluid (CSF) neurofilament light protein (NFL) – a marker of neuronal injury – in people living with HIV (PLHIV). Elevated levels of homocysteine is an indicator of B12 and/or folate deficiency. The aim of this study was to investigate if B-vitamin substitution would lead to decreased levels of plasma NFL

Methods

We performed a single center, randomised, open, controlled trial in Gothenburg, Sweden. Neuroasymptomatic PLHIV with stable antiretroviral therapy (ART) for > 12 months and with HIV RNA <50 copies/mL who consented to participate in the study were screened. Individuals who had plasma homocysteine > 12 µmol/L were eligible for the study. Patients were randomised to either treatment with Triobe (cyanocobalamin 0,5 mg, folic acid 0,8 mg, and pyridoxine 3 mg) or to no treatment for 12 months. P-homocysteine levels were analysed with stable isotope dilution liquid chromatography tandem mass spectrometry. P-NFL concentration was measured using an in-house Single molecule array method.

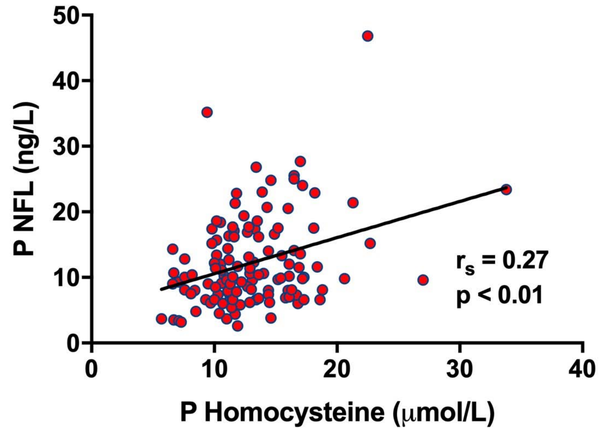

Figure 1. Baseline correlation between plasma NFL and plasma Homocysteine
In a cohort of PLHIV on stable ART treatment.

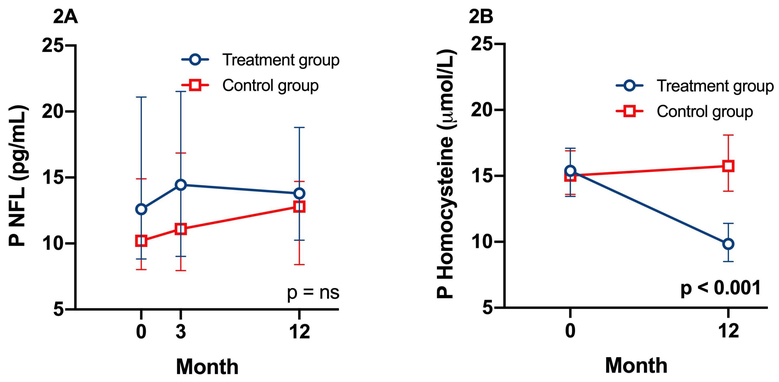

Figure 2a-b. a) Median plasma NFL before and after 12 months of Triobe treatment
b) Median plasma homocysteine before and after 12 moths of Triobe treatment.

Results

One hundred and twenty-four PLHIV matching the inclusion citeria were screened for p-homocysteine levels. There was a significant correlation between p-homocysteine levels and p-NFL levels at screening (r = 0.27, p < 0.01).

Sixty-one patients were randomised to either treatment with Triobe (n = 31) or to no treatment (n = 30). One participant in the B-vitamin arm, and two in the control arm discontinued the study before 12 months.

P-homocysteine levels decreased from a median of 15.9 (interquartile range (IQR) 13. 5–17.2) to 9.9 (IQR 8.5–11.4) (p < 0.001) between baseline and month 12 in PLHIV receiving B-vitamin substitution, but not in controls: 14.6 (IQR 13.4–16.9) and 16 (IQR 13.9–18) at baseline and month 12, respectively.

At baseline, median plasma NFL was 12.6 (IQR 8.8–21.1) pmol/L in the B-vitamin arm and 10.2 (IQR 8.02–14.9) in the control arm. The levels did not change significantly to month 12 in either arm, 13.8 (IQR 10.3-18.8) and 12.8 (IQR 8.4–14.7) pmol/L, respectively.

The study will continue until 12 months of follow-up.

For additional information please contact: Erika Ahlgren
Email: erika.ahlgren@gu.se

HIV Clinical Research Center
Department of Infectious Diseases
REGION VÄSTRA GÖTALAND SAHLGRENSKA UNIVERSITY HOSPITAL
UNIVERSITY OF GOTHENBURG