

PubMed

Abstract ▾

Full text links



Am J Med. 2013 Feb;126(2):141-9. doi: 10.1016/j.amjmed.2012.06.022. Epub 2012 Dec 5.

## Metanx in type 2 diabetes with peripheral neuropathy: a randomized trial.

Fonseca VA<sup>1</sup>, Lavery LA, Thethi TK, Daoud Y, DeSouza C, Ovalle F, Denham DS, Bottiglieri T, Sheehan P, Rosenstock J.

### + Author information

#### Abstract

**PURPOSE:** To determine whether a combination of L-methylfolate, **methylcobalamin**, and pyridoxal-5'-phosphate (LMF-MC-PLP [Metanx; Pamlab LLC, Covington, La]) improves sensory neuropathy.

**RESEARCH DESIGN AND METHODS:** This multicenter, randomized, double-blind, placebo-controlled trial involved 214 patients with type 2 diabetes and neuropathy (baseline vibration perception threshold [VPT]: 25-45 volts), who were randomly assigned to 24 weeks of treatment with either L-methylfolate calcium 3 mg, **methylcobalamin** 2 mg, and pyridoxal-5'-phosphate 35 mg or placebo. The primary end point was effect on VPT. Secondary end points included Neuropathy Total Symptom Score (NTSS-6) and Short Form 36 (SF-36), as well as plasma levels of folate, vitamins B(6) and B(12), methylmalonic acid (MMA), and homocysteine.

**RESULTS:** There was no significant effect on VPT. However, patients receiving LMF-MC-PLP consistently reported symptomatic relief, with clinically significant improvement in NTSS-6 scores at week 16 ( $P=.013$  vs placebo) and week 24 ( $P=.033$ ). Improvement in NTSS scores was related to baseline MMA and inversely related to baseline PLP and metformin use. Quality-of-life measures also improved. Homocysteine decreased by  $2.7\pm 3.0$   $\mu\text{mol/L}$  with LMF-MC-PLP versus an increase of  $0.5\pm 2.4$   $\mu\text{mol/L}$  with placebo ( $P=.0001$ ). Adverse events were infrequent, with no single event occurring in  $\geq 2\%$  of subjects.

**CONCLUSIONS:** LMF-MC-PLP appears to be a safe and effective therapy for alleviation of peripheral neuropathy symptoms, at least in the short term. Additional long-term studies should be conducted, as the trial duration may have been too short to show an effect on VPT. In addition, further research on the effects in patients with cobalamin deficiency would be useful.

Copyright © 2013 Elsevier Inc. All rights reserved.

#### Comment in

A medicinal food provides food for thought in managing diabetic neuropathy. [Am J Med. 2013]

PMID: 23218892 [PubMed - indexed for MEDLINE]



Publication Types, MeSH Terms, Substances, Secondary Source ID



LinkOut - more resources



## PubMed Commons

 0 comments

[How to join PubMed Commons](#)