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Wax-matrix extended-release niacin vs inositol hexanicotinate: A comparison of wax-matrix, extended-release niacin to inositol hexanicotinate ‘‘no-flush’’ niacin in persons with mild to moderate dyslipidemia

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Abstract

BACKGROUND:

Nicotinic acid (NA), long used for the treatment of dyslipidemia, has shown problems with undesirable side effects and safety issues. Wax-matrix, extended-release niacin (WMER) and inositol hexanicotinate (IHN) have both been formulated to increase patient tolerability. Several trials of WMER demonstrated good efficacy in improving dyslipidemia; however, there are few scientific data on the use of IHN.

OBJECTIVE:

This study was designed to compare the efficacy and tolerability of WMER and IHN to each other and placebo to help clinicians make an informed choice of NA agents.

METHODS:

This was a 6-week blinded, placebo-controlled trial comparing 1500 mg/d of WMER with 1500 mg/d IHN. Subjects with mild-to-moderate dyslipidemia (low-density lipoprotein 130– 190/dL) were randomized, after a 4-week diet lead-in period, to three parallel study arms (40 subjects/ arm). Diet, pill compliance, and side effects were monitored as well as lipid and blood chemistry profiles (baseline, 6 weeks). A dose-reduction protocol was included for subjects who did not tolerate the 1500-mg dose of NA. A pharmacokinetic substudy was conducted on subjects from the WMER (n 5) and IHN (n 5) groups.

RESULTS:

WMER demonstrated significant improvements in total cholesterol -11%, lowdensity lipoprotein -18%, high-density lipoprotein +12%, and non–high-density lipoprotein -15% (P ,.001), whereas IHN and placebo showed no significant improvement in lipids. All groups had good medication compliance and treatment tolerance with only one dropout in the WMER group as the result of flushing. Blood chemistries showed small (24%–27%) mean increases in hepatic transaminases; six subjects completed the study at reduced dosage protocol with good lipid results. Pharmacokinetics demonstrated an intermediate release and absorption rate for WMER over 6 hours and IHN showed no evidence of bioavailability.

CONCLUSION:

WMER demonstrated good tolerance and efficacy and extended-release kinetics. IHN was well tolerated but was no better than placebo in lipid improvement and showed no evidence of bioavailability.