

# Palliative Care & Clinical Trials and Pharmacovigilance

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## Efficacy of N-SORB® a proprietary KD120 MEC metabolically activated enzyme formulation: A randomized, double-blind, placebo-controlled study

Rui Guo<sup>1</sup>, Sreejayan Nair<sup>1</sup>, Derek Smith<sup>2</sup>, Bledar Bisha<sup>3</sup>, Rama Nair<sup>4</sup>, Bernard W Downs<sup>5</sup>, Steve Kushner<sup>6</sup>, Debasis Bagchi<sup>5,7</sup> and Manashi Bagchi<sup>8</sup>

<sup>1,2,3,4</sup>University of Wyoming, USA

<sup>5</sup>Victory Nutrition International Inc, USA

<sup>6</sup>ALM R&D, USA

<sup>7,8</sup>University of Houston, USA

**Background:** Enzymes are crucial for all aspects of metabolic function. Digestive enzymes from natural sources have been credited with beneficial effects in the digestion and absorption of food. N-SORB is a novel KD120 multienzyme complex (MEC) of metabolically activated enzymes composed of proteases, amylases, lipases, alpha-galactosidase, and glucoamylase from natural sources. These enzymes are encapsulated in a SK713 SLP (non-GMO soy lecithin phospholipid) absorption technology (Prodosome®).

**Objective:** This randomized, double-blind placebo-controlled investigation assessed the safety and efficacy of N-Sorb in healthy male and female volunteers on blood parameters, immunity, body composition, physical health, and quality of life (QOL).

**Methods:** Forty-six male and female (mean age: 25.8 - 12.1 years) healthy volunteers, were randomly assigned to receive either N-SORB (1 mL, twice daily) or placebo for 90 consecutive days. Complete blood count, as well as blood glucose, liver enzymes, and lipid profile were assessed pre- and post-intervention. Serum cytokine levels were determined by using a Bio-Plex Pro Human Cytokine 8-plex assay. Whole body composition analysis was performed by dual-energy X-Ray absorptivity (DEXA) to determine body fat mass, lean mass and android and gynoid fat. Body weight, blood pressure, and physical health were assessed. Changes in quality of life

was examined using the World Health Organization QOL-abbreviated version (WHOQOL-BREF) and sleep quality was assessed using the 24-item Pittsburgh Sleep Quality Index (PSQI) questionnaire. Adverse events were monitored.

**Results:** A total of 40 subjects successfully completed the study. Compared to placebo, changes in blood cell counts including haematocrit, haemoglobin, mean corpuscular volume, platelets and lymphocytes provide evidence of some improvement. QOL parameters showed a small but significant improvement in the N-SORB group. A significant increase was observed in AST level in the placebo group at the end of 90 days of treatment, however, no increase was observed in the N-SORB group. No significant changes in BUN, serum creatinine, ALP, ALT, and lipid profile were observed.

**Conclusion:** This study demonstrates that short-term intervention with N-SORB improves the QOL and PSQI in healthy volunteers and marginally improved cardiometabolic parameters, lipid profile or body composition. No adverse effects were reported.

### Speaker Biography

Manashi Bagchi is the professor in the University of Houston College of Pharmacy at USA. Her research interest is clinical pharmacy.

e: [mbagchi08@gmail.com](mailto:mbagchi08@gmail.com)

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