

Blood sugar improves with first gastrointestinal microbiome modulator, NM504

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In adults with prediabetes, a new drug that alters microbial populations and their environment in the gastrointestinal (GI) tract improves glucose tolerance—the body's response to consuming carbohydrates— after four weeks of treatment and without a change in diet. These results, from a pilot study, will be presented Monday at the joint meeting of the International Society of Endocrinology and the Endocrine Society: ICE/ENDO 2014 in Chicago.

The not-yet-named therapeutic, NM504, is the first in a new class of therapies known as GI microbiome modulators. The GI microbiome—the mix of microbial and associated physical and chemical factors in the digestive system—may play a critical part in regulating the body's metabolism, some researchers believe. There is recent scientific evidence that microbial imbalance, or dysbiosis, in the gut contributes to the development of Type 2 diabetes.

"We believe that modern Western diets contribute to development of Type 2 diabetes, in part because they change the habitat of the microorganisms that reside in the gut. This shifts the microbial populations that live there in ways that affect metabolic health," said Mark Heiman, PhD, the study's principal investigator. Heiman is chief scientific officer for MicroBiome Therapeutics, the Colorado-based biotechnology company that is developing NM504 and sponsored the study.



NM504 is designed to shift the GI bacteria and other microorganisms—called microbiota—and their environment in specific ways to achieve improved health outcomes, according to Heiman. He said the drug contains concentrated bioactive food ingredients: inulin, a fiber; beta-glucan and polyphenolic antioxidant compounds.

Heiman and colleagues conducted a study in 28 adults with prediabetes, a frequent precursor to Type 2 diabetes. Fourteen subjects were randomly assigned to receive NM504 twice a day, and the other 14 were assigned to receive placebo, or "dummy" material. Neither the subjects nor the investigators were aware of the drug assignments. Before any treatment and again at four weeks of treatment, all subjects had an oral glucose challenge. In this test, they drank a concentrated glucose (sugary) drink and then had their <u>blood sugar levels</u> tested at various times and compared with pretest levels.

Blood sugar levels at 120 and 180 minutes after the glucose challenge were significantly lower in subjects who took NM504 than those who received the placebo, Heiman reported. Also during this test, NM504 increased insulin sensitivity, the body's ability to successfully clear glucose from the bloodstream.

Compared with placebo, NM504 treatment also decreased the desire to eat, which Heiman said Microbiome Therapeutics' researchers had hoped the therapeutic would do. He said the subjects tolerated NM504 well, with only a mild increase in flatulence, or gas.

"This work indicates a new therapeutic target—the GI microbiome—that has the potential to revolutionize the treatment of metabolic diseases such as Type 2 diabetes," Heiman commented.

MicroBiome Therapeutics reports that the company plans to develop NM504 and/or a closely related therapeutic as a prescription medicine to



treat prediabetes and diabetes.

Provided by The Endocrine Society

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