NestléHealthScience

News release

Nestlé Health Science Announces Initiation of Year-Long OPTI-WIN Clinical Trial for Weight Loss and Maintenance

Efficacy of OPTIFAST® Program in maintaining weight loss to be measured against a standard lifestyle intervention

Florham Park, N.J. (November 5, 2015) – Nestlé Health Science announced today it will begin enrolling participants in a new clinical trial on its OPTIFAST® Program. This year-long study, named OPTI-WIN*, will evaluate the effectiveness of the OPTIFAST Program on weight loss and maintenance in comparison with a modified Diabetes Prevention Program, a recognized standard lifestyle intervention. The announcement comes during ObesityWeek 2015 (November 2-6, Los Angeles), the largest gathering of physicians, surgeons and other healthcare professionals from around the world dedicated to the latest research and care of people with obesity.

“Obesity is a complex health issue, and experts agree successful weight loss requires a mix of behavioral lifestyle counseling, changes to the diet and exercise,” said Jamy Ard, M.D., principal investigator of OPTI-WIN and Associate Professor of Epidemiology and Prevention at Wake Forest Baptist Medical Center, who also serves as U.S. Medical Director for the OPTIFAST Program. “This trial will provide a fresh look at OPTIFAST and how it compares to a current standard of care for those looking to lose weight and keep it off.”

OPTIFAST is a comprehensive weight management program that incorporates medical monitoring, complete meal replacements, behavior modification and lifestyle education. The program utilizes OPTIFAST meal replacement products to achieve the prescribed amount of calories and micronutrients per day. It is a non-surgical option designed for people with a Body Mass Index (BMI) greater than 30.

“OPTIFAST reinforces the need for holistic approaches to help people not only lose weight, but maintain a healthy weight over time,” said Juan Ochoa, M.D., Chief Medical Officer for Nestlé Health Science in the United States. “For four decades, OPTIFAST has been proven effective, and more than 80 peer-reviewed publications have documented its results. OPTI-WIN will further add to this depth of science.”

OPTI-WIN Clinical Trial Details
OPTI-WIN will be a 52-week, open, randomized controlled trial. The study will compare the OPTIFAST Program against a food-based control group. Three hundred adults with obesity, ages 18 to 70, and with BMIs between 30 kg/m^2 and 55 kg/m^2, will be enrolled and randomly assigned to either the OPTIFAST or food-based group.

The OPTIFAST group will undergo a portion-controlled, nutritionally-balanced weight loss phase with meal replacements of shakes, bars and soups. This phase will be followed by a gradual reintroduction of food. The food-based group will receive a modified Diabetes Prevention Program diet, specifically with an energy deficit diet based on the American Diabetes Association standards of diabetes care and education, and will meet recommendations endorsed by the American College of Cardiology, the American Heart Association Task Force on Practice Guidelines, The Obesity Society and the American Association of Family Practitioners.[1] In addition to the respective dietary interventions, both groups will participate in behavioral counseling sessions as well as a moderate exercise program.

Effectiveness of the **OPTIFAST® Program compared **WI**th a reduced-e**N**ergy, food-based diet plan on body weight*

The trial will compare these two groups for the degree of weight loss throughout the 52-week study period. Additionally, it will evaluate weight loss maintenance and percentage of patients who reach their treatment goals, as well as behavioral changes, physical activity levels and other measures. OPTI-WIN will be conducted across 10 sites in the United States. Enrollment is expected to be completed by June 2016.

About OPTIFAST®

The OPTIFAST Program was developed in 1974 to fill the growing need to address obesity in a healthy, effective way. As diseases related to obesity became more prevalent, and more people began seeking a solution, the OPTIFAST Program was introduced as a sensible option for lifestyle transformation. The program combines support and counseling, lifestyle education, and medical monitoring with meal replacements to help people lose weight, which can in turn reduce weight-related health risks. Medical supervision is a key component of the program. The OPTIFAST Program is offered by Nestlé Health Science and is available in key markets worldwide. For more information, to see patient stories and to find a clinic, visit www.optifast.com.

About Nestlé Health Science

Nestlé Health Science, a wholly-owned subsidiary of Nestlé, is a health-science company engaged in advancing the role of nutritional therapy to change the course of health for consumers, patients and our partners in healthcare. Its portfolio of nutrition solutions, supported variously by proprietary diagnostics and devices, targets a number of health areas, such as inborn errors of metabolism, pediatric and acute care, obesity care, healthy aging as well as gastrointestinal and brain health. Through investing in innovation and leveraging leading edge science, we bring forward innovative nutritional therapies with proven clinical, health economic value and quality of life benefits. Nestlé Health Science employs around 3,000 people worldwide and is headquartered in Epalinges (near Lausanne), Switzerland. For more information, please visit www.nestlehealthscience.us.

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Reference:

1. Jensen et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. J Am Coll Cardiol. 2014 Jul 1;63(25 Pt B):2985-3023.

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