**Clinical Trials Update**

**Mediterranean Diet vs Low-fat Diet for Patients With Heart Disease**

In the largest and longest trial to evaluate a Mediterranean diet for secondary prevention of cardiovascular disease, the eating plan was superior to a low-fat diet.

Conducted at a single center in Spain, the trial involved 1002 patients with coronary heart disease—82.5% of whom were men—and an average age of 59.5 years. The participants were randomly assigned to follow a Mediterranean diet or a low-fat diet intervention, and both groups received continuous dietary support over the 7-year study. The primary outcome was a composite of major cardiovascular events, including myocardial infarction, revascularization, ischemic stroke, peripheral artery disease, and cardiovascular death.

As reported in *The Lancet*, 17.3% of participants in the Mediterranean diet group and 22.2% of those in the low-fat diet group experienced the primary end point. Among men, the primary end point occurred in 16.2% of those assigned to the Mediterranean diet group and 22.8% of those assigned to the low-fat diet. The researchers found no difference in outcomes between the diets for the women in the study.

**Lifestyle Intervention Improves Frail Older Adults’ Mobility**

Frail older adults lost less mobility, muscle mass, and strength over 3 years when they participated in an intervention that combined moderate-intensity physical activity with technological support and nutritional counseling, researchers reported in *The BMJ*.

The multisite trial included 1519 people in Europe with an average age of 78.9 years who had physical frailty and sarcopenia. These were defined by low muscle mass and a score of 3 to 9 on the short physical performance battery (SPPB), with lower scores indicating poorer physical function on the 0- to 12-point scale.

Participants randomly assigned to the intervention participated in twice-weekly group exercises, at-home exercises up to 4 times per week periodically monitored with a wearable device, and personalized nutritional counseling for 36 months. The control group received education on healthful aging in a single monthly group session.

The intervention had a positive effect for the frailest participants. For participants with an SPPB score of 3 to 7, mobility disability—defined as an inability to independently walk 400 m in less than 15 minutes—occurred in 46.8% of the intervention group compared with 52.7% of the control group. Women in the intervention group also lost less muscle strength and muscle mass than those in the control group. Falls, however, were more prevalent in the intervention group.

**Single-Dose Clindamycin Gel Highly Effective for Bacterial Vaginosis**

A single dose of vaginal clindamycin gel successfully treated most women with bacterial vaginosis, including those with recurrent disease, a recent trial reported. The US Food and Drug Administration approved the bioadhesive extended-release gel, marketed as Xacitio, in 2021 to treat bacterial vaginosis. The recent study, published in *Obstetrics & Gynecology*, assessed efficacy based on the percentage of participants who were considered clinically cured.

The study randomly assigned 307 women with bacterial vaginosis to the 2% clindamycin gel or to placebo. Participants were evaluated at screening, at day 7 to 14, and at day 21 to 30.

In the modified intention-to-treat population, 70.5% of women in the clindamycin group and 35.6% in the placebo group achieved clinical cure at day 21 to 30. The clinical cure rate was 70% for women in the intervention group who’d had more than 3 bacterial vaginosis episodes in the prior year. Adverse events related to treatment, most commonly vulvovaginal candidiasis, occurred among 15.3% of participants in the clindamycin group.

**Oral Baricitinib Restores Hair Loss in Alopecia Areata**

Treatment with oral baricitinib, a Janus kinase inhibitor, resulted in hair regrowth among patients with alopecia areata, 2 phase 3 trials published in the *New England Journal of Medicine* demonstrated.

A total of 1200 adults with severe alopecia areata were randomized to receive 4 mg of baricitinib, 2 mg of baricitinib, or placebo once daily. The primary outcome was a Severity of Alopecia Tool (SALT) score of 20 or less at week 36. SALT scores range from 0 to 100, with higher scores indicating more scalp hair loss. More than half of the trial’s participants scored 95 to 100 at baseline.

The estimated percentages of patients who achieved the primary outcome in the 2 trials were 35.9% and 38.8% with 4-mg baricitinib, 19.4% and 22.8% with 2-mg baricitinib, and 3.3% and 6.2% with placebo.

Common adverse events associated with the treatment were acne, upper respiratory tract and urinary tract infections, headache, and elevated creatine kinase levels. Increases in low- and high-density lipoprotein cholesterol levels occurred among some patients who received baricitinib. The trials will continue for up to 200 weeks to gather additional data on longer-term adverse events. – Anita Slomski

Note: Source references are available through embedded hyperlinks in the article text online.