Clinical Trials Update

No Benefit for Lopinavir–Ritonavir in Severe COVID-19

Treatment with the HIV combination drug lopinavir–ritonavir did not accelerate recovery or improve mortality rates among hospitalized patients with severe coronavirus disease 2019 (COVID-19), a trial in the New England Journal of Medicine reported.

The study’s 199 patients with confirmed severe acute respiratory syndrome coronavirus 2 infection were randomly assigned to receive standard care plus 400 mg of lopinavir and 100 mg of ritonavir twice a day for 14 days or standard care alone.

For both groups the time to clinical improvement—the primary end point—was a median of 16 days. Researchers stopped the intervention early for 13 patients who experienced mainly gastrointestinal adverse events.

Daily Aspirin Not Neuroprotective in ASPREE Trial

Daily low-dose aspirin does not reduce the risk of dementia, mild cognitive impairment (MCI), or cognitive decline, according to a secondary analysis of the Aspirin in Reducing Events in the Elderly (ASPREE) trial, published in Neurology.

The study’s 19,114 healthy participants, aged 65 to 98 years, were randomized to receive daily 100 mg of aspirin or placebo and were followed up for a median of 4.7 years. The rates of clinically probable and possible Alzheimer disease, MCI, and cognitive decline were similar between the 2 groups.

A dementia diagnosis or MCI occurred among 488 participants in the aspirin group and 476 in the placebo group. Cognitive decline occurred among 838 participants in the aspirin group and 816 participants in the placebo group. Cognitive change over time was also similar among both groups.

Participants stopped the ASPREE study 6 months early for futility. Earlier findings from the same cohort showed that low-dose aspirin did not prolong disability-free survival or reduce all-cause dementia over 5 years but did increase the risk of major hemorrhage.

Integrated Care Cut Mortality in Patients With Atrial Fibrillation

An integrated-care intervention conducted in primary care practices reduced all-cause mortality among elderly patients with atrial fibrillation (AF), a noninferiority trial in the European Heart Journal demonstrated.

The study randomized 26 primary care practices (1240 patients with a median age of 77 years) in the Netherlands to provide integrated care or usual care. In the integrated care group, trained primary care nurses at 15 practices performed quarterly AF check-ups, including providing patient education, monitoring anticoagulation therapy, and facilitating consultations with cardiologists and anticoagulation clinics.

After a median follow-up of about 2 years, 7.4% of patients in the intervention group had died compared with 13.5% in the usual care group. The all-cause mortality rate was 3.5 per 100 patient-years in the intervention group compared with 6.7 per 100 patient-years in the control group.

The authors attributed the decrease in mortality to early detection of complications and clinical deterioration, demonstrated by fewer urgent hospitalizations.

Gabapentin Treats Alcohol Use Disorder With Withdrawal Symptoms

Gabapentin prevented heavy drinking and promoted alcohol abstinence among patients with alcohol use disorder (AUD) and a history of alcohol withdrawal symptoms in a trial in JAMA Internal Medicine.

Study participants had AUD and current or prior alcohol withdrawal symptoms and were not receiving other alcohol-related treatment. After 3 abstinent days, 96 participants were randomly assigned to receive oral gabapentin or a placebo.

Participants received nine 20-minute medical management visits over the 16-week treatment period. A marker of heavy drinking—the percentage of disialo carbohydrate-deficient transferrin in the blood—was collected monthly during treatment.

In the gabapentin group, 27% of participants had no heavy drinking days, defined as 5-plus standard drinks per day for men and 4-plus drinks for women, compared with 9% of the placebo group. Total abstinence was also higher in the gabapentin group—18%, compared with 4% in the placebo group. Those with greater alcohol withdrawal symptoms benefitted the most from gabapentin. However, about one-third of participants in each group did not complete the trial, a major limitation.

Psoriasis Drug Guselkumab Improved Psoriatic Arthritis Symptoms

Guselkumab, a biologic drug approved to treat patients with moderate or severe psoriasis, significantly and safely improved psoriatic arthritis, a phase 3 trial in The Lancet concluded. Guselkumab is a human monoclonal antibody that inhibits interleukin-23.

The trial’s 741 biologic-naive participants were randomly assigned to receive subcutaneous injections of 100 mg of guselkumab every 4 weeks; 100 mg guselkumab at weeks 0 and 4 and then every 8 weeks; or a placebo. The primary end point was American College of Rheumatology 20% (ACR20) improvement response.

At 24 weeks, 64% of participants in both guselkumab dosing regimens achieved an ACR20 response compared with 33% of the placebo group. Serious adverse events occurred among 3% of patients receiving guselkumab every 4 weeks, 1% of patients receiving guselkumab every 8 weeks, and 3% of the placebo group. —Anita Slomski

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