Clinical Trials Update

Elagolix Reduces Fibroid-Related Heavy Menstrual Bleeding Long-term

Elagolix, a gonadotropin-releasing hormone antagonist, plus hormonal add-back therapy reduced heavy menstrual bleeding from uterine leiomyomas during up to 12 months of continuous treatment, according to a trial in *Obstetrics & Gynecology*.

The phase 3 extension study enrolled 433 women in the US and Canada who had completed 6 months of treatment with either elagolix plus estradiol and norethindrone acetate or elagolix alone in 2 preceding phase 3 trials. The extension study continued the same treatment for an additional 6 months.

At 1 year, 87.9% of the add-back therapy group and 89.4% of the elagolix-alone group met the primary end point—the percentage of women with less than 80 mL of menstrual blood loss during the final month and a 50% or greater reduction in menstrual blood loss from baseline to the final month. Add-back therapy attenuated hot flushes, night sweats, and bone mineral density loss associated with the use of elagolix alone.

Aspirin Fails to Prevent Depression in Older Adults

Low-dose aspirin did not reduce the risk of depression in healthy older adults, a trial in *JAMA Psychiatry* reported. Depression is associated with elevated markers of inflammation, which may occur before symptoms arise, particularly in older people.

The study's 19 114 participants, whose mean age was 75 years, were randomly assigned to receive 100 mg/d of aspirin or placebo. The trial was a substudy of the Aspirin in Reducing Events in the Elderly (ASPREE) trial, which found that aspirin did not increase dementia- and disability-free life span in healthy older people.

After a median follow-up of 4.7 years, the aspirin and placebo groups had no significant difference in their annual scores for major depressive disorder.

"This lack of efficacy is compounded by a clear increase in the risk of bleeding events documented in previous reports from this study," the authors wrote.

Shorter Resident Shifts May Not Improve Patient Safety

Residents who worked schedules that eliminated extended shifts made a greater number of serious errors than those who worked schedules with shifts of 24 or more hours, a trial in the *New England Journal of Medicine* reported.

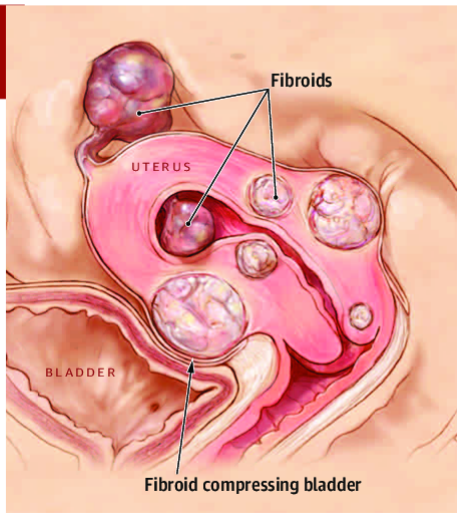
The randomized crossover trial compared the different schedules at 6 US pediatric intensive care units (ICUs). Residents on the intervention schedule cycled through day and night shifts of 16 hours or less. The control schedule included extended shifts of 24 hours or more. Residents worked each schedule for 12 months, including a 4-month wash-in interval.

On average, residents saw about 2 more patients on the intervention schedules than on the control schedules, which may explain the greater number of serious errors in the intervention group—97.1 per 1000 patient-days compared with 79 per 1000 in the control group. When researchers adjusted the data for resident workload, intervention schedules did not show a greater number of errors.

Mailings, Phone Calls Increase Post-MI Cardiac Rehabilitation

Most patients aren't referred to cardiac rehabilitation after a myocardial infarction (MI), and about half discontinue their medication by 1 year. A scalable intervention designed to promote secondary prevention treatments after MI increased patients' cardiac rehabilitation but not their medication adherence, a trial in the *BMJ* reported.

The study's 2632 patients from 9 Canadian cardiac centers were randomized to receive 1 of 3 options: mailed booklets encouraging participation in rehabilitation and stressing the importance of long-term cardiac medications, mailed educational materials plus automated phone calls to screen for nonadherence followed by personal calls if necessary, or to usual care.



Elagolix and hormonal therapy reduced heavy menstrual bleeding from uterine fibroids in a recent study.

Among patients in the mail and phone group, 37% completed cardiac rehabilitation compared with 32% in the mail-only group and 27% in the usual care group.

Aspirin Protects Against Colorectal Cancer in Lynch Syndrome

Daily aspirin use for at least 2 years significantly reduced colorectal cancer risk among patients with Lynch syndrome, according to the 10-year follow-up of a randomized trial. Aspirin's protective effect did not become apparent until about 5 years after beginning treatment, the investigators reported in *The Lancet*.

The international trial randomly assigned 861 patients with Lynch syndrome to receive 600 mg/d of aspirin or placebo for 2 to 4 years. Cancer outcomes were monitored for at least 10 years and up to 20 years for some participants.

In the aspirin group, 9% of patients developed colorectal cancer compared with 13% of the placebo group. Aspirin did not, however, prevent other Lynch syndrome–related cancers, including endometrial, ovarian, and pancreatic cancers.

Both groups averaged 45 years old and had similar adverse events; the risk of gastrointestinal bleeding would likely be much greater in an older population, according to the authors. **– Anita Slomski, MA**

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

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