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Jordan Drug Information and Toxicology Center 2023

2023

Oral isotretinoin therapy for acne and risk for inflammatory bowel disease (march 2023)

Data regarding oral isotretinoin and the risk for subsequent development of inflammatory bowel disease (IBD) continue to increase:

In a retrospective cohort study of electronic health data from over 150,000 patients, patients given oral isotretinoin for acne and patients given oral antibiotics for acne had similar lifetime risks for Crohn disease and ulcerative colitis, with an increase in risk for ulcerative colitis in the isotretinoin group limited to the first six months of therapy.

In a second retrospective cohort study of electronic health data from over 850,000 patients, risk for incident IBD within one year did not differ between patients with acne treated with oral isotretinoin and patients with acne who did not receive systemic therapy or who received oral antibiotic therapy. However, there was an association between acne itself and risk for incident IBD. These **findings support the concept that oral isotretinoin therapy may not have a clinically meaningful impact on risk for IBD.** [1]

Nicotinamide for the treatment of hyperphosphatemia in chronic kidney disease (April 2023)

Treatment of hyperphosphatemia in patients with chronic kidney disease (CKD) begins with dietary phosphate restriction of 900 mg/day. If hyperphosphatemia persists with dietary restriction, we administer phosphate binders.

Nicotinamide, a widely available and inexpensive metabolite of nicotinic acid (niacin, vitamin B3), has generated interest as a potential treatment for hyperphosphatemia in patients with end-stage kidney disease. However, in a placebo-controlled randomized trial including over 700 patients on hemodialysis, add-on nicotinamide therapy had only a short-term effect on phosphate levels that was not maintained at 52 weeks .In addition, nicotinamide therapy was associated with higher rates of diarrhea, pruritus, and thrombocytopenia. Based on these results, we **do not use nicotinamide to treat hyperphosphatemia in patients on dialysis.** [2]

Caffeine consumption and congenital anomalies (May 2023)

The safety of caffeine consumption during pregnancy is an ongoing concern. An update of the 1997-2011 US National Birth Defects Study compared children born with versus without congenital anomalies stratified by maternal self-reported pre- and early pregnancy caffeine intake and found associations with 10 congenital anomalies . However, **causality is unlikely** given the lack of dose-response relationships, small effect size (odds ratios 1.2 to 1.7), residual confounding, retrospective subjective ascertainment of caffeine consumption, likelihood of chance due to the large number of estimates, and other study limitations. **We continue to suggest that individuals who are attempting to conceive or pregnant limit caffeine consumption to less than 200 to 300 mg per day until more conclusive data are available**.[3]

Aspirin and risk of acute rejection after liver transplantation (April 2023)

Whether aspirin use mitigates the risk of acute T-cell mediated rejection after liver transplantation is uncertain. In a cohort study comparing daily, low-dose aspirin use with no aspirin in over 2000 liver transplant recipients, aspirin use was associated with higher rates of rejection-free survival after one, three, and five years (89, 87, and 84 percent versus 82, 81, and 80 percent, respectively) . **Aspirin was not associated with increased bleeding complications**. Although these data are promising, **additional evidence is needed to confirm efficacy and safety before aspirin prophylaxis can be routinely recommended in liver transplant recipients**.[4]

References:

1. Oral isotretinoin therapy for acne and risk for inflammatory bowel disease (March 2023) , accessed online via uptodate. , cited on 28 may 2023.
2. Nicotinamide for the treatment of hyperphosphatemia in chronic kidney disease (April 2023) , accessed online via uptodate , cited on 28 may 2023
3. Caffeine consumption and congenital anomalies (May 2023), , accessed online via uptodate. , cited on 28 may 2023
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Vitamin B12 supplementation does not reduce preterm birth (April 2023)

Cohort studies have reported that **lower maternal vitamin B12 levels (particularly gross deficiency) are associated with a higher risk of preterm birth, suggesting that supplementation may improve pregnancy outcome**. However, in a placebo-controlled randomized trial of vitamin B12 supplementation during pregnancy conducted in Nepal in which most participants were at least marginally vitamin B12 deficient, supplementation did not improve gestational age at birth or birth weight . For individuals with vitamin B12 deficiency, which is uncommon in the United States, **vitamin B12 supplementation is indicated for maternal health**. It is administered parenterally if malabsorption is the cause and orally to those with normal absorption.[1]

FDA warning on selective androgen receptor modulators in some supplements (May 2023)

Selective androgen receptor modulators (SARMs) are found in some supplements labeled as natural testosterone replacements or used for muscle-building. SARMs cannot be legally marketed as dietary supplements in the United States. **The US Food and Drug Administration recently issued a consumer warning because of increasing reports of SARM-related adverse events, such as liver injury (predominantly cholestatic) and hallucinations** . This warning reinforces our approach to advise patients to **avoid pre-workout and muscle-building supplements and to ask patients with unexplained liver injury about supplement use**.[2]

Timing of aspirin discontinuation in preeclampsia prophylaxis (March 2023)

The **optimal time to discontinue aspirin use for preventing preeclampsia is unclear, and practice varies**. In a randomized trial in Spain, patients at high risk of preterm preeclampsia based on a first-trimester screening algorithm began aspirin 150 mg daily before 14 weeks of gestation . Blood angiogenic factors were measured at 24 to 28 weeks, and those at low preeclampsia risk based on these results discontinued aspirin prophylaxis. The rates of preterm and term preeclampsia and most adverse outcomes were not significantly different for the two groups, but the early discontinuation group had less minor antepartum bleeding (7.6 versus 12.3 percent). These findings warrant further study. They are not generalizable to populations such as the United States, where angiogenic factor testing is unavailable, a lower dose of aspirin (81 mg) is commonly used, and the population is more diverse. [3]

Expanded recommendations for hepatitis B virus screening in adults (April 2023)

Screening for hepatitis B virus (HBV) in adults has traditionally been recommended for those with risk factors . In March 2023, the United States Centers for Disease Control and Prevention **expanded their recommendations to include** universal screening for persons ≥18 years of age at least once during their lifetime, regardless of risk . The rationale is the prevalence of chronic HBV infection in the general population (0.4 percent), the low vaccination rates in adults, and the harms of missed infection such as fulminant hepatitis and liver cancer. Testing should include hepatitis B surface antigen, hepatitis B surface antibody (anti-HB), and total hepatitis B core antibody. We support universal screening; however, **screening is generally not needed if an HBV vaccine series has been completed and there is serologic evidence of immunity (anti-HBs ≥10 milli-international units/mL).[**4]

Respiratory syncytial virus vaccination in pregnancy (April 2023)

Respiratory syncytial virus (RSV) is a major cause of morbidity and mortality in infants; however, no RSV vaccines are approved for use in pregnancy in the United States. In a phase 3 placebo-controlled randomized trial including almost 7000 pregnant people between 24 and 36 weeks of gestation, a single intramuscular injection of RSV prefusion F protein-based vaccine reduced the rate of severe RSV-associated lower respiratory tract illness in infants up to 180 days after birth . The rate of nonsevere RSV-associated illness also trended lower. Rates of preterm birth trended higher in the vaccinated compared with unvaccinated group, but this was not statistically significant. These data **suggest effective passive immunity in infants. The US Food and Drug Administration is reviewing an application for approval of this vaccine.** [5]

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References:

1. Vitamin B12 supplementation does not reduce preterm birth (April 2023), accessed online via uptodate, cited on 28 may 2023.
2. FDA warning on selective androgen receptor modulators in some supplements (May 2023)accessed online via uptodate, cited on 22 march 2023.
3. Timing of aspirin discontinuation in preeclampsia prophylaxis (March 2023), accessed online via uptodate, cited on 22 march 2023.
4. Expanded recommendations for hepatitis B virus screening in adults (April 2023), accessed online via uptodate, cited on 22 march 2023.
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