December

Better Pharmacist Knowledge

Jordan Drug Information and Toxicology Centre 2023

2023

Valacyclovir for prevention of congenital cytomegalovirus infection (October 2023)

For pregnant patients with periconception or first-trimester primary cytomegalovirus infection, **we suggest high-dose oral valacyclovir rather than no therapy.** Emerging evidence suggests that maternal administration of valacyclovir for primary cytomegalovirus (CMV) infection substantially reduces the risk of congenital CMV infection, especially if begun prior to 14 weeks of gestation and within 8 weeks of the maternal infection. In a 2023 individual patient data meta-analysis, maternal valacyclovir administration upon diagnosis of periconception or first-trimester primary CMV infection was associated with a 66 percent reduction in congenital CMV (11 versus 25 percent). **We suggest high-dose oral valacyclovir (8g per day) for patients with a primary CMV infection in early pregnancy after a comprehensive discussion of the potential benefits and risks (eg, 2 percent risk of reversible maternal kidney failure).** [1]

Immunoprophylaxis for severe respiratory syncytial virus in infants (October 2023)

In all infants younger than eight months who are born during the respiratory syncytial virus (RSV) season or are entering their first RSV season, we recommend one dose of nirsevimab prophylaxis rather than no prophylaxis (Grade 1B), unless the birthing parent received RSV vaccination at least 14 days prior to birth. Nirsevimab is a new monoclonal antibody that targets the prefusion conformation of the respiratory syncytial virus (RSV) F glycoprotein. It has a longer half-life than palivizumab, an existing antibody that requires five monthly injections to provide immunoprophylaxis against severe RSV infection. The efficacy and safety of nirsevimab were demonstrated in two randomized placebo-controlled trials, one involving 1490 infants ≥35 weeks' gestation and the other involving >1400 preterm infants (29 to <35 weeks' gestation). **In both trials, a single intramuscular dose of nirsevimab lowered rates of RSV-related medical evaluation and hospital admissions for RSV**.

we now recommend that infants <8 months old receive one dose of nirsevimab during their first RSV season if the birthing parent did not receive RSV vaccination between 32 and 36 weeks of gestation and at least 14 days prior to delivery. Palivizumab may be used in high-risk infants if nirsevimab is not available.[2]

تعميم صادر عن المؤسسة العامة للغذاء والدواء

اشارة الى معلومات المأمونية الدوائية الخاصة بالدواء الصيدلاني (Ustekinumab) Stelara® وذلك حسب نتيجة ل results external significant safety issue of a post marketing observational study in patients with psoriasis final registry report

وعليه نحيطكم علما بما يلي:

Ustekinumab have the potential to increase the risk of malignancy, The risk of malignancy may be higher in psoriasis patients who have been treated with other biologics during the course of their disease.

Cardiovascular events including myocardial infarction and cerebrovascular accident have been observed in patients with psoriasis exposed to Stelara in a post marketing observational study. Risk factors for cardiovascular disease should be regularly assessed during treatment with Stelara.

علما أنه تم مخاطبة الوكيل لتحديث النشرة الداخلية الخاصة بالمستحضر لاضافة المعلومات الوارد أعلاه.[3]

Uncertain role for inhaled antibiotics in prevention of ventilator-associated pneumonia (November 2023)

Whether inhaled antibiotics are effective in preventing ventilator-associated pneumonia (VAP) is **unclear**. In a randomized trial of 850 patients on mechanical ventilation for 72 to 96 hours, daily inhaled amikacin for the next 3 days reduced the 28-day incidence of VAP compared with placebo (15 versus 22 percent) but did not reduce the number of days on mechanical ventilation, days of antibiotic utilization, or mortality. **While promising, the lack of benefit for patient-important outcomes reduces our confidence in the preventive value of inhaled antibiotics, and thus we have not adopted this practice in our intensive care units.** [4]

References:

1. Valacyclovir for prevention of congenital cytomegalovirus infection (October 2023), accessed online via uptodate. , cited on 3 Dec 2023.
2 Immunoprophylaxis for severe respiratory syncytial virus in infants (October 2023), accessed online via uptodate, cited on 3 Dec 2023
3. JFDA website
4. Uncertain role for inhaled antibiotics in prevention of ventilator-associated pneumonia (Nov 2023), accessed online via uptodate, cited on 4 Dec 2023

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Investigational nemolizumab for prurigo nodularis (November 2023)

Treatment of prurigo nodularis (PN), a chronic skin disorder characterized by severe pruritus and multiple itchy nodules predominantly located on the extremities, is aimed at interrupting the itch-scratch cycle. In a phase 3, randomized trial that included 274 adults with moderate-to-severe PN, improvement in itch and skin appearance at 16 weeks, as measured by validated scoring systems, was greater for patients assigned to subcutaneous nemolizumab (an antagonist of interleukin-31, a cytokine linked to pruritus) than those assigned to placebo. Adverse events in the nemolizumab group included exacerbation/new onset of atopic dermatitis and peripheral or facial edema. These findings, along with a prior small trial, indicate that nemolizumab has efficacy for the treatment of PN, although its use remains investigational. [1]

Early metformin treatment of gestational diabetes mellitus (November 2023)

Usual initial gestational diabetes mellitus (GDM) care (ie, medical nutritional therapy, exercise) may result in a few weeks of hyperglycemia before a need for pharmacotherapy is established. In a randomized trial evaluating whether initiating metformin at the time of GDM diagnosis regardless of glycemic control improves clinical outcomes compared with usual care, the metformin group had a lower rate of insulin initiation and favorable trends in mean fasting glucose, gestational weight gain, and excessive fetal growth, but more births <2500 grams. Rates of preeclampsia, neonatal intensive care unit admission, and neonatal hypoglycemia were similar for both groups. Given these mixed results, **we recommend not initiating metformin at the time of GDM diagnosis except in a research setting.**[2]

Tranexamic acid for burn wound excision (November 2023)

Randomized trials have established that tranexamic acid (TXA) reduces blood loss and transfusion requirements in various surgical settings, but data are **limited.** In a meta-analysis of observational studies evaluating intravenous and topical TXA in burn surgery, use of TXA was associated with reductions in blood loss, use of intraoperative transfusion, and number of units transfused but no change in venous thromboembolism or mortality rates.

Based on this review and data from other surgical settings, **we routinely administer intravenous TXA for burn wound excisions over 20 percent of total body surface area.** [3]

No benefit to routinely adding vancomycin for prophylaxis before joint replacement (November 2023)

For preoperative prophylaxis in patients undergoing joint replacement, vancomycin is sometimes added to cefazolin to empirically cover methicillin-resistant staphylococci. In a randomized trial of over 4000 patients undergoing joint replacement, **the rate of surgical site infection was similar following prophylaxis with cefazolin plus vancomycin compared with cefazolin plus placebo** (4.5 versus 3.5 percent). There were no differences in rates of infection due to methicillin-resistant Staphylococcus aureus (MRSA) or Staphylococcus epidermidis. **We continue to use cefazolin alone for prophylaxis in patients undergoing joint replacement who are not known to have MRSA colonization or infection**.[4]

Adverse effects with piperacillin-tazobactam versus cefepime (November 2023)

Observational data have raised concerns for nephrotoxicity with **piperacillin-tazobactam** (when given with **vancomycin**) and neurotoxicity with **cefepime**. In an open-label trial of over 2500 patients randomly assigned to piperacillin-tazobactam versus cefepime, the incidence of major kidney events was comparable between groups, including among the 1900 patients who also received vancomycin. Median antibiotic use was three days. Although the incidence of neurotoxicity (primarily delirium) was higher with cefepime (21 versus 17 percent), imbalances in baseline delirium rates reduce confidence in that finding. These data reduce concern for nephrotoxicity with short-term coadministration of piperacillin-tazobactam and vancomycin. **For those who warrant prolonged therapy with vancomycin plus an antipseudomonal agent, we weigh the uncertain risks of nephrotoxicity and neurotoxicity when choosing between piperacillin-tazobactam and cefepime.** [5]

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References:

1. Investigational nemolizumab for prurigo nodularis (Nov 2023), accessed online via Medscape, cited on 3 Dec 2023.
2. Early metformin treatment of gestational diabetes mellitus (Nov 2023), accessed online via Medscape, cited on 3 Dec 2023.
3. Tranexamic acid for burn wound excision (Nov 2023), accessed online via uptodate, cited on 4 Dec 2023.
4. No benefit to routinely adding vancomycin for prophylaxis before joint replacement (Nov 2023), accessed online via uptodate, cited on 4 Dec 2023.
5. Adverse effects with piperacillin-tazobactam versus cefepime (Nov 2023), accessed online via uptodate, cited on 4 Dec 2023.

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