CHIPS REGIMEN

Drug Information News Letter
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NEW GUIDELINES FOR OSTEOPOROSIS TREATMENT

- *Osteoporosis is a systemic skeletal disease characterized by decreasing bone mass and deterioration of bone tissue that leads to an increased risk for bone fragility and fracture, especially in the hip, spine, and wrist. ACP's guideline focuses on the comparative benefits and risks of short- and long-term drug treatments for low bone density or osteoporosis, including prescriptions, calcium, vitamin D, and estrogen. ACP recommends in an evidence-based clinical practice guidelines (published in **Annals of Internal Medicine**) that women with osteoporosis should be treated with Bisphosphonates (Alendronate, Risedronate, or Zoledronic acid) or Denosumab, a biological agent.*

- ✔ *First-line treatment to treat osteoporosis include Alendronate, Risedronate, Zoledronic acid, and Denosumab. All of these agents have good evidence in reducing the risks for vertebral, hip, and nonvertebral fractures.*
- ✔ *Ibandronate is not recommended because of insufficient data regarding its effects on the risk for hip fracture.*
- ✔ *Raloxifene does not appear to reduce the risk for nonvertebral or hip fracture. The relatively new combination of Bazedoxifene with estrogen lacks data on fracture prevention.*
- ✔ *Estrogen treatment can improve BMD during treatment, but does not prevent fracture among women with established osteoporosis. The authors specifically recommend against the use of estrogen and raloxifene in the treatment of osteoporosis.*
- ✔ *The effect of calcium and vitamin D on the risk for fracture is uncertain, as is the effect of physical activity.*
- ✔ *The treatment period for osteoporosis should be 5 years, but continuation of treatment past 5 years may be considered after shared decision making regarding the risks and benefits associated with therapy.*
- ✔ *BMD monitoring during treatment has generally not been associated with improved outcomes. Therefore, such testing is unnecessary during the 5-year treatment period.*
- ✔ *Despite a low level of evidence, the ACP recommends treatment with bisphosphonates among men with recognized osteoporosis in order to prevent vertebral fracture.*

Reference: *http://www.medscape.org/viewarticle/880273*

PROBIOTICS AND WEIGHT LOSS

- *An area of increasing interest is the role of the gut microbiota on weight loss and obesity. The gut flora seems to play an important role in metabolic processes, with one indicator being that diet substantially influences the composition of gut flora. For example, a more diverse or complex diet results in a more diverse flora. Of note, the makeup of gut flora differs between lean and obese people, with overweight and obese people tend to have a less diverse gut flora.*
- *Animal studies have shown that probiotics can have an impact on weight. Some probiotics have been linked to weight gain and some to weight loss. Several preliminary clinical studies have begun to evaluate the impact of probiotic supplements and foods on measures of weight and body fat in humans; however, many are limited by small study populations and short treatment durations. Individual study findings have been largely inconsistent.*
- *Comprehensive meta-analysis of randomized controlled trials that evaluated adults and children who were lean, normal weight, or obese at baseline. The analysis included 14 randomized controlled trials in adults and found that probiotic interventions brought about significant changes in weight-related outcomes. The results, reported as a standardized mean difference (SMD) with a confidence interval of 95%, suggested a medium treatment effect of reducing weight in adults (SMD -0.54 [-0.83, -0.25]). In a subset of eight studies, which consistently reported BMI outcomes, an absolute mean difference was calculated and determined to be -0.43 (-0.54, -0.33).*
- *Probiotic species included were Lactobacillus acidophilus, L casei, L plantarum, L gasseri, L rhamnosus, L bulgaricus, Bifidobacterium infantis, B lactis, B longum, B breve, Streptococcus thermophilus, and Saccharomyces cerevisiae.*
- *At this point, it is clear that the gut microbiota plays a role in a variety of physiological processes and also probably affects body weight and fat. The question remains, though, as to whether taking a probiotic-containing product can alter the microbiota in such a way as to cause desirable anthropomorphic changes.*

Reference: *http://www.medscape.com/viewarticle/882777*

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TODAY'S MUST WATCH

The following are few important drugs approved by US FDA during the month APRIL - JUNE 2017.

BRAND	DRUG	INDICATION
Bevyxxa	Betrixaban	Prophylaxis of Venous Thromboembolism.
Baxdela	Delafloxacin	Treatment of acute bacterial skin and skin structure infections.
Rhofade	Oxymetazoline hydrochloride	Treatment of facial erythema associated with rosacea.
Tymlos	Abaloparatide	Treatment of postmenopausal women with osteoporosis at high risk for fracture.
Austedo	Deutetrabenazine	Treatment of chorea associated with Huntington's disease.
Ingrezza	Valbenazine	Treatment of tardive dyskinesia.
Zerviate	Cetirizine ophthalmic solution 0.24%	Treatment of ocular itching associated with allergic conjunctivitis.
Kevzara	Sarilumab	Treatment of active rheumatoid arthritis.

- **Betrixaban** is specifically indicated for the prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE. It is a factor Xa (FXa) inhibitor. It selectively blocks the active site of FXa and does not require a cofactor (such as Anti-thrombin III) for activity.

  Reference: https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm564422.htm

- **Delafloxacin** is a fluoroquinolone antibacterial agent. It is specifically indicated for use in adults for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI).

- **Abaloparatide** is a human parathyroid hormone related peptide [PTHrP(1-34)] analog. It is specifically indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture.

  Reference: http://www.centerwatch.com/drug-information/fda-approved-drugs/drug/100201/tymlos-abaloparatide

- **Deutetrabenazine** is a vesicular monoamine transporter 2 (VMAT2) inhibitor. It is specifically indicated for the treatment of chorea associated with Huntington's disease. The precise mechanism is believed to be related to its effect as a reversible depletor of monoamines (such as dopamine, serotonin, norepinephrine, and histamine) from nerve terminals.

  Reference: http://www.centerwatch.com/drug-information/fda-approved-drugs/drug/100197/austedo-deutetrabenazine.

- **Valbenazine** is a vesicular monoamine transporter 2 (VMAT2) inhibitor. Its mechanism of action in treating tardive dyskinesia is thought to be mediated through the reversible inhibition of vesicular monoamine transporter 2 (VMAT2), a transporter that regulates monoamine uptake from the cytoplasm to the synaptic vesicle for storage and release.

  Reference: http://www.centerwatch.com/drug-information/fda-approved-drugs/drug/100198/ingrezza-valbenazine

STUDENTS CORNER

A CRITICAL STEP IN POLIO ERADICATION

Polio Eradication and Endgame Strategic Plan 2013-2018 calls for an important transition in the vaccines used to eradicate polio and requires the removal of all oral polio vaccines (OPV's) in the long term. This will eliminate the rare risk of Vaccine – Associated Paralytic Polio (VAPP) and circulating Vaccine – Derived Polio Virus. The withdrawal of OPV's must occur in a globally synchronized manner, starting in April 2016 with a switch from trivalent OPV (tOPV) to bivalent OPV (bOPV), removing the type 2 component (OPV2) from immunization programmes.

Advantages : bOPV offers the same advantages as OPV. In addition,

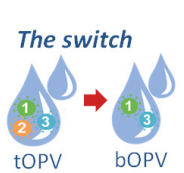
- For both types 1 & 3 polio, bOPV is more effective than OPV and almost as good as the monovalent vaccines, yet in a package that delivers both at once.
- bOPV allows countries to simplify vaccine logistics and optimize protection.
- In areas where access to children is limited, using bOPV helps maximize the impact of each contact with a child.

Efficacy : bOPV is at least 30% more effective than tOPV and almost as good as the respective monovalent OPV's

Preparation for the removal of OPV's also includes the introduction of at least one dose of inactivated polio vaccine (IPV) into routine immunization programmes in all countries and was started during end of 2015.

Reference:
- ✔ *http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/oral_polio_vaccine/en*
- ✔ *http://polioeradication.org/polio-today/polio-prevention/the-vaccines/opv*

POLIO GLOBAL ERADICATION INITIATIVE



EVERY LAST CHILD

CLINICAL CONNECTION

Drug safety communication: Canagliflozin comes with RISK-CANVAS.

- The U.S. Food and Drug Administration (FDA) has concluded that the type 2 diabetes medicine Canagliflozin (Invokana, Invokamet, Invokamet XR) causes an increased risk of leg and foot amputations.
- Final results from two clinical trials – the CANVAS (Canagliflozin Cardiovascular Assessment Study) and CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants With Type 2 Diabetes Mellitus) – showed that leg and foot amputations occurred about twice as often in patients treated with Canagliflozin compared to patients treated with placebo, which is an inactive treatment. The CANVAS trial showed that over a year's time, the risk of amputation for patients in the trial were equivalent to:
  - ✔ 5.9 out of every 1,000 patients treated with Canagliflozin
  - ✔ 2.8 out of every 1,000 patients treated with placebo
- The mechanism by which Canagliflozin may increase the risk of amputation is still unclear. An increased risk has not been seen in studies with other medicines in the same class, Dapagliflozin and Empagliflozin. However, data available to date are limited and the risk may also apply to these other medicines. Further data are expected from ongoing studies with Canagliflozin, Dapagliflozin, and Empagliflozin.

Reference : www.fda.gov/Safety/MedWatch/SafetyInformation

Drug safety communication: Pancreatitis with Eluxadoline

- The U.S. Food and Drug Administration (FDA) is warning that Viberzi (Eluxadoline), a medicine used to treat irritable bowel syndrome with diarrhea (IBS-D), should not be used in patients who do not have a gallbladder. An FDA review found these patients have an increased risk of developing serious pancreatitis that could result in hospitalization or death. Pancreatitis may be caused by spasm of a certain digestive system muscle in the small intestine.
- FDA received 120 reports of serious cases of pancreatitis or death. Among the 68 patients who reported their gallbladder status, 56 of them did not have a gallbladder and received the currently recommended dosage of Viberzi. Seventy-six patients were hospitalized, of which two patients died.
- Physicians can consider both over-the-counter (OTC) or FDA-approved prescription medicines to treat symptoms associated with IBS-D such as OTC Bismuth Subsalicylate (Kaopectate and Pepto-Bismol), OTC Loperamide (Imodium), and prescription medicine Diphenoxylate/Atropine (Lomotil) for diarrhea in all the cases where Eluxadoline is not recommended.

Reference:*https://www.fda.gov/Drugs/DrugSafety/ucm546154.htm*

ADVICE

Do You Feel **DEPRESSED** *often, Stay Away from these* **4** *things*

Avoid Staying Alone

When you are depressed, you might not feel pleasure in things you used to enjoy earlier. This might result in social isolation, making you lonelier and more depressed than ever. But living in social situations, meeting people will actually help you. It can take off your mind from the feelings of depression and while meeting people might not seem as enjoyable as it did before, it can certainly help in overcoming the feelings of loneliness.

Avoid White Foods

Processed foods or white foods are simple carbohydrates that can actually lead to insulin dumping and trigger the process of depression. The surge of insulin will initially make you feel happier, but once that's surge goes down, you will begin to feel depressed again. This will even trigger hunger and particular cravings, which in turn affect depression symptoms negatively.

Avoid NOT Seeking Help

Most of the people are unable to differentiate between sadness and depression. But if you are someone who has been feeling intensely sad for no reason, then you are probably depressed. So, don't avoid seeking help. Approach a therapist, even online if you want more confidentiality and privacy. A counselor can actually help in overcoming the feeling of depression.

Products with Aspartame

Aspartame is an artificial, non saccharide sweetener used as sugar substitute in majority of sugar free foods and beverages. It can lower the production of serotonin, a neurotransmitter that's associated with mood. Therefore, eating aspartame can increase the intensity of your depression symptoms, may result in insomnia as well.

STAFF PUBLICATIONS

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3. T. N. V. Ganesh Kumar, S. Vidyadhara, T. D. Kumar, D. Jaswanth, K. Vijetha and B. G. Priyadarshini. Development and Validation of a Novel Colorimetric Method for the Estimation of Emtricitabine in Bulk and Tablet Formulation. Indian Journal of Pharmaceutical Sciences, Vol. 78, Issue 6: 775-779.
4. J. Subba Rao, S. Vidyadhara, S. Siva Prasad, B Praveen Kumar, A. Rajashekar and K. Anusha. Stability indicating studies of Rasagiline Mesylate in bulk and dosage form by RP-HPLC method. The Pharma Review, March- April, 2017: 133-137.
5. J. Subba Rao, S. Vidyadhara, J. Ramesh Babu and B. Venkateswara Rao. Novel UV Spectrophotometric and RP-HPLC method development and validation for the determination of Glimipride in bulk and pharmaceutical Formulation. Inventi Impact: Pharm Analysis & Quality Assurance vol. 2017, Issue 2: 50-55.
6. T. Balakrishna, S. Vidyadhara, T.E.G.K Murthy, R.L.C. Sasidhar and S. Vikas. Formulation and evaluation of fast dissolving buccal films of Sumatriptan Succinate. International Journal of ChemTech Research. Vol. 10, Issue-6: 545-552

Graduation Day Celebrations at CHIPS (12-04-2017)

Annual Day Celebrations at CHIPS (13-04-2017)

International Yoga Day Celebration at CHIPS (21-06-2017)

CHIPS students qualified in NIPER JEE - 2017

We are Glad to Receive your Feedback to chipsregimen@gmail.com

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