Clinical Pharmacy Newsletter

A Newsletter of Drug and Prescribing Information
Published by
Clinical Pharmacy Services Department, Govt. Head Quarters Hospital, Ooty
(A Unit of Department of Pharmacy Practice, JSS College of Pharmacy, Ooty)

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VOLUME XXV ISSUE01 JANUARY-MARCH 2019

Diet Soda Linked to Increased Risk for Diabetic Retinopathy

Drinking diet soda may increase the risk for proliferative diabetic retinopathy — a severe type of diabetic eye disease that can lead to blindness — according to a study published online in the September/October 2018 issue of *Clinical and Experimental Ophthalmology*.

The study is the first to evaluate the link between soft drink consumption and micro vascular complications of diabetes. "In our clinical sample of people with diabetes, consuming more than four cans, or 1.5 liters, of diet soft drinks per week was associated with a twofold increased risk of having proliferative diabetic retinopathy," first author Eva Fenwick, PhD, told *Medscape Medical News*. Fenwick is a clinical research fellow at the Singapore Eye Research Institute and an assistant professor at the Duke-NUS Medical School, Singapore. Interestingly, the study did not find a correlation between consumption of regular, sugar-sweetened soft drinks and increased risk for diabetic retinopathy. Because the study was cross-sectional, further longitudinal studies are needed to determine whether soft drinks are unhealthy alternatives to sugar-sweetened beverages, she added.

Diet soft drinks have been marketed as a healthier option to regular soft drinks, yet a growing body of evidence has suggested that artificial sweeteners may also have detrimental health effects. Past research has linked diet soda to increased cardio-metabolic risk, poor cardiovascular outcomes, and type 2 diabetes mellitus. Although the biological mechanism remains unknown, some researchers hypothesize that diet beverages may "fake out" the body to assume more energy has been consumed than it really has. That may lead to increased hunger and higher calorie intake in the long run. The study included 609 adults with type 1 diabetes (n = 73; 12.5%), type 2 diabetes (n = 510; 87.5%), or unknown diabetes type (n = 26; 4.3%) at a tertiary eye hospital between 2009 and 2010. The mean age of the participants was 64.6 years. They came from the Diabetes Management Project, a cross-sectional study of English-speaking adults with diabetes in Melbourne, Australia. Participants underwent objective measurement of diabetic retinopathy and diabetic macular edema with standardized techniques to determine how soft drinks may affect micro vascular complications of diabetes.

Participants self-reported soft drink consumption on a 145-question food frequency questionnaire. Of the total sample,46.8% (n = 285) drank regular soft drinks, and 31.2% (n = 190) drank diet soft drinks. Almost one quarter (24%) (n = 146) had proliferative diabetic retinopathy. Compared with no consumption, high levels of diet soft drink consumption (more than four 375-mL cans/bottles per week)were independently linked to an approximately 2.5 times increased odds of having proliferative diabetic retinopathy (Odds Ratio, 2.51; 95% confidence interval, 1.05 – 5.98). The researchers adjusted results for traditional diabetic retinopathy risk factors, such as diabetes duration, smoking, and body mass index. Regular soft drink consumption was not linked to diabetic macular oedema and the presence or severity of diabetic retinopathy.

The authors note that this last result is consistent with past research. Some studies have found a link between consumption of diet soft drinks, but not regular soft drinks, and vascular complications of diabetes. Others have failed to confirm these findings. The authors mention several explanations for this discrepancy.

The study was cross-sectional, the researchers could not determine whether people who reported current diet soda consumption had previously drunk regular soda and whether they changed their lifestyle after being diagnosed with diabetic retinopathy. Although the analysis adjusted for changes in dietary habits during the past 5 years, such behaviour could have led to an overestimation of the association between diet soda and diabetic retinopathy.

"Although the results of our study must be interpreted within the context of several limitations, they add to the growing body of literature on the harmful effects of diet drinks on a range of health outcomes, including CVD [cardiovascular disease],diabetes, and metabolic syndrome," Fenwick said.

"Given that diet soft drinks are perceived as a healthy alternative to regular soft drinks, clinicians and patients should be aware that diet soft drinks may not be without risks of their own," she concluded.

Source: https://www.medscape.com/viewarticle/907086

Stelara vs Humira: What's the difference?

Stelara (ustekinumab) and Humira (adalimumab) are two biological medicines that doctors use to treat immune system conditions. They have different effects on the body and some different benefits and risks. Biological medicines, or biologics, are a class of drugs composed of naturally occurring molecules, such as sugars and proteins. Some biologics contain living cells or tissues. Manufacturers design these drugs to replicate proteins and other molecules that the body naturally produces. Doctors use ustekinumab and adalimumab to treat a number of autoimmune diseases, including psoriatic arthritis and Crohn's disease. Read on to learn about the similarities and differences of Stelara and Humira as treatments for various conditions.

What is adalimumab?

Humira is a brand name for the biological medicine adalimumab. Doctors use this medicine to treat a number of long-term illnesses that impact the immune system. These include psoriatic arthritis, which affects the joints, and Crohn's disease, which affects the digestive system.

People with these conditions have higher levels of a protein called tumour necrosis factor alpha. This causes inflammation in the body. Adalimumab works by attaching to these proteins and stopping them from working. This can reduce the inflammation that causes many of the conditions' symptoms.

What is ustekinumab?

Stelara is the brand name for the biological medicine ustekinumab. Like adalimumab, doctors use this medicine to treat autoimmune conditions, which are diseases that affect the immune system. Ustekinumab works by targeting two proteins in the body, interleukin-12 (IL-12) and interleukin-23 (IL-23). In healthy people, IL-12 and IL-23 cause temporary inflammation to help the body fight infection. In people with psoriatic arthritis or Crohn's disease, the body produces too much IL-12 and IL-23, causing excess inflammation when it is not needed. Ustekinumab works by attaching to the proteins and blocking their activity.

How are these medicines different?

The two medicines both impact the immune system, but in different ways. There are similarities and differences in the ways that both drugs work, their side effects, and their risks as treatments for various medical conditions, which we discuss below.

How they work

Both medicines dampen the activity of the immune system. This reduces the inflammation that can cause the symptoms of autoimmune diseases. Also, doctors prescribe both drugs for long-term use.

Crohn's disease

Large studies of adalimumab as a treatment for Crohn's disease have shown that, initially, around 6 in 10 people respond well to the drug. After taking adalimumab for a year, more than 1 in 3 people from this group had not experienced a flare-up of the disease.

Trials of ustekinumab for Crohn's disease found that the drug could benefit around 50% of people with the condition. After starting this treatment, some people no longer need to use steroids to control Crohn's disease symptoms.

Psoriatic arthritis

In clinical trials, 57% of adult participants with psoriatic arthritis who took adalimumab for 6 months experienced at least a 20% improvement in their symptoms.

Studies involving usetkinumab as a treatment for the condition found that 50% of adult participants experienced at least a 20% improvement after 6 months.

Side effects

Like all medicines, adalimumab and ustekinumab can cause side effects, though it is important to note that not everyone experiences them. Common side effects of adalimumab can include:

Skin reactions around the injection site, such as pain, swelling, or itching. Respiratory infections, such as a cold, a sinus infection, or pneumonia, Stomach pain, headache, feeling nauseous and possibly vomiting, rash, Musculoskeletal pain

People taking adalimumab may also experience infections, dehydration, mood swings, depression, and difficulty sleeping. Common side effects of ustekinumab are similar to those of adalimumab. They include:

Upper respiratory infections, Vomiting, headache, Vaginal yeast infections, Tiredness, Urinary tract infections, Itching

In some people, the drug can cause lung inflammation. Symptoms of this include shortness of breath and a cough that does not go away. People who experience these symptoms should see a doctor right away. As with many medicines, biologics can trigger allergic reactions. Anyone who notices the following symptoms of a serious allergic reaction should seek urgent medical attention:

Feeling faint, Chest tightness, Swelling of the face, eyelids, tongue, or throat, Hives

Risks

Both medicines block the activity of the immune system. This can be risky because it reduces the body's natural defenses. It can increase the chances of a person contracting a serious infection, such as tuberculosis (TB) or pneumonia. Health-care professionals tend to closely monitor people taking these drugs, in order to spot any early signs of infection. Doctors advise individuals who take biologics not to receive live vaccines.

How to take them

A person takes either ustekinumab or adalimumab over a long period of time. Individuals receive these medicines by injection. Biologics would not survive in the gut, so people cannot take them as pills. A health-care professional will usually give a person an injection pen so that they can inject themselves. The exact dose depends on individual factors, including the severity of the condition.

Alternatives

Adalimumab and ustekinumab treat mild-to-moderate symptoms of Crohn's disease, psoriatic arthritis, and various other autoimmune diseases. Health-care professionals can recommend a number of other options to people with these conditions. Other treatments include steroids and nonsteroidal anti-inflammatory drugs, such as ibuprofen. Because of the risks associated with taking adalimumab or ustekinumab, doctors tend only to prescribe them when other treatments have failed.

Takeaway

Adalimumab and ustekinumab are biological medications that doctors use to treat autoimmune diseases such as Crohn's disease and psoriatic arthritis. The drugs work by dampening the immune system and reducing the inflammation that leads to many of the symptoms of these long-term conditions. Doctors prescribe them when other forms of treatment have failed. They are effective, but not without risks. These biologics can leave people unable to fight off serious infections, such as TB and pneumonia. A health-care team will closely monitor individuals on these medications to make sure that they notice and treat any infections early.

Source:https://www.mdlinx.com/internal-medicine/top-medical-news/article/2019/03/14/7560691

EVENT CORNER

REPORT

Highlights of the Department of Pharmacy Practice:

Ms. B.S. Roopa, Thomas Eipe, Divya P, Prince E Wilfred, Kezia Sam and Regil C Varghese presented a paper on 'Correlation of antenatal depression among the iron and vitamin D deficient pregnant women' at '4th International Conference on Clinical Pharmacy Transitioning towards Multidisciplinary care and Research' organized by Department of Pharmacy Practice Manipal College of Pharmaceutical Sciences Manipal Academy of Higher Education, Manipal on 5th -6th January 2019.

Dr. S. Ponnusankar acted as Resource person and delivered a talk on 'How to write a world class manuscript (?)' at One day seminar on Accentuation of a well-structured manuscript organized by DevakiAmma Memorial College of Pharmacy, Chelembra, Kerala on 13th February 2019.

Ms. Roopa B.S. acted as Resource person and delivered a talk on 'Narrative review, Systematic Review and Meta-Analysis' at One day seminar on Accentuation of a well-structured manuscript organized by DevakiAmma Memorial College of Pharmacy, Chelembra, Kerala on 13th February 2019.

Mr. Vishwas.H.N acted as Resource person and delivered a Guest lecture on 'Drug induced ocular diseases' at Creative Educational Society's College of Pharmacy, Kurnool, Andhra Pradesh on 18th February 2019.

Dr. Khayati Moudgil, Clinical Resident received Rs. 50,000/- Research grant to carry out a Minor project on Chronic obstructive pulmonary disease from JSS Academy of Higher Education & Research, Mysuru in February 2019.

Dr. S. Ponnusankar acted as a Resource person and delivered a talk on 'Updates in fields of Pharmacy' during the AICTE sponsored Quality improvement program at Delhi institute of Pharmaceutical Sciences & Research, Government of NCT of Delhi dated 25th -29th March 2019.

Dr. K..P. Arun acted as a Resource person and delivered a talk on 'Teaching & Learning principles: Learning styles for new generation students' during PCI sponsored Continuing Education Program organized by Seven Hills College of Pharmacy, Andhra Pradesh dated 14th -16th March 2019.

Dr. K..P. Arun acted as a Resource person and delivered a talk on 'Precision Medicine' during National seminar 'Recent Trends and Opportunities for Clinical pharmacists' organized by Department of Pharmacy practice, JKK MMRF's – Annai JKK sampooraniAmmal college of Pharmacy , Tamil Nadu on 23rd March 2019

Dr. K..P. Arun acted as a Resource person and delivered a talk on 'New Paradigms in Teaching- Learning Process' during Continuing Education Program organize by Al Shifa college of Pharmacy, Kerala dated 25-27th March 2019.

Ms. M. Deepalakshmi received the 'Best coordinator award' during 'World TB day celebrations-2019' from the District Health society-RNTCP, Ooty on 24th March 2019.

AICTE sponsored Quality improvement program on Pharm D Education: Training for the academic practitioners dated 1st-14th March, 2019

Department of Pharmacy Practice, JSS College of Pharmacy, Ooty organized AICTE Sponsored QIP on Pharm D Education: Training for the academic practitioners dated 1st-14th March 2019. About 30 faculty participated in the Program. Dr. S. Ponnusankar acted as Coordinator and Dr. K.P. Arun acted as Joint Coordinator for the QIP. Participants from Tamil Nadu, Karnataka, Andhra Pradesh, Telangana, Kerala, Gujarat and Maharashtra participated in the QIP. Experts from Industry and Academia trained the QIP participants.

Dr. S Ponnusankar acted as a Resource person and delivered talk on 'Clinical Pharmacy Services- Our experiences at Public Care Hospital' and 'Research Manuscript communication- How to write a world class manuscript and how to find a journal' during the AICTE sponsored 'Quality Improvement Program (QIP) on Pharm D Education: Training for the academic practitioners' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty dated 1st-14th March 2019.

Dr. K.P. Arun acted as a Resource person and delivered talk on 'Pharmacokinetics and Pharmacometrics' during the AICTE sponsored 'Quality Improvement Program (QIP) on Pharm D Education: Training for the academic practitioners' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty dated 1st-14th March 2019.

Ms. M. Deepalakshmi acted as a Resource person and delivered talk on 'Integrated Teaching' and 'Objective structured clinical examination' during the AICTE sponsored 'Quality Improvement Program (QIP) on Pharm D Education: Training for the academic practitioners' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty dated 1st-14th March 2019.

Ms. B.S. Roopa acted as a Resource person and delivered talk on 'Project work for V.Pharm. D Students' and 'Block Teaching method of delivery of curriculum for V Pharm D students' during the AICTE sponsored 'Quality Improvement Program (QIP) on Pharm D Education: Training for the academic practitioners' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty dated 1st-14th March 2019.

Mr. C. Jayakumar acted as a Resource person and delivered talk on 'ICT-enabled teaching methods' during the AICTE sponsored 'Quality Improvement Program (QIP) on Pharm D Education: Training for the academic practitioners' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty.

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Dr. G. K. Sadagoban acted as a Resource person and delivered talk on 'Pharm Academic- Experiential Learning Management System' during the AICTE sponsored 'Quality Improvement Program (QIP) on Pharm D Education: Training for the academic practitioners' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty dated 1st-14th March 2019.

Dr. C. Keerthana acted as a Resource person and delivered talk on 'Internship Evaluation & Assessment' during the AICTE sponsored 'Quality Improvement Program (QIP) on Pharm D Education: Training for the academic practitioners' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty dated 1st-14th March 2019.

Dr. Khayati Moudgil acted as a Resource person and delivered talk on 'Clerkship Evaluation & Assessment' during the AICTE sponsored 'Quality Improvement Program (QIP) on Pharm D Education: Training for the academic practitioners' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty dated 1st-14th March 2019.

Dr. Aneena Suresh acted as a Resource person and delivered talk on 'Evidence based medicine' during the AICTE sponsored 'Quality Improvement Program (QIP) on Pharm D Education: Training for the academic practitioners' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty dated 1st-14th March 2019.

Mr. Vishwas. H.N. acted as a Resource person and delivered talk on 'How to use POWERPOINT effectively' and 'Basics & Execution of few Statistical Tests in SPSS' during the AICTE sponsored 'Quality Improvement Program (QIP) on Pharm D Education: Training for the academic practitioners' organized by Department of Pharmacy Practice, JSS College of Pharmacy, Ooty dated 1st-14th March 2019.

DRUG PROFILE

BREXANOLONE

Class: Neuroactive steroid gamma-amino butyric acid (GABA) A receptor positive modulator

Indication: Treatment of postpartum depression (PPD) in adults

Mechanism of Action:
Mechanism of action not fully understood. However, drug is thought to be related to positive allosteric modulation of GABA-A receptors.

Dosage form and Administration: Brexanolone is available in the form of Injection. Each single dose vial contains Brexanolone 100 mg/20 mL (5 mg/mL) .
Drug requires dilution prior to administration. After dilution, the product can be stored in infusion bags under refrigerated conditions for up to 96 hours. However, diluted product can be used for only 12 hours at room temperature.
Brexanolone should be administered through separate peristaltic infusion pump through separate line. Other drugs should not be administered through this line. PVC, non-DEHP, non-latex infusion sets to be used for drug administration. In-line filter infusion sets should not be used.
Brexanolone is administered as a continuous intravenous infusion over 60 hours as follows:

- 0 to 4 hours: Initiate with a dosage of 30 mcg/kg/hour
- 4 to 24 hours: Increase dosage to 60 mcg/kg/hour
- 24 to 52 hours: Increase dosage to 90 mcg/kg/hour (alternatively consider a dosage of 60 mcg/kg/hour for those who do not tolerate 90 mcg/kg/hour)
- 52 to 56 hours: Decrease dosage to 60 mcg/kg/hour
- 56 to 60 hours: Decrease dosage to 30 mcg/kg/hour

Dosing in Renal & Hepatic Impairment:
Dosage adjustment in patients with hepatic impairment is not necessary. Dosage adjustment is not required in mild, moderate or severe renal impairment. Brexanolone should be avoided in patients with end stage renal disease with GFR of < 15 mL/minute/1.73 m^2 because of the potential accumulation of the solubilizing agent (Betadexsulfobutyl ether sodium).

Pharmacokinetics: Post intravenous administration, the peak plasma concentration of Brexanolone (Mean study state) is 52 ng/mL (at 60 mcg/kg/hr) and 79 ng/mL (at 90 mcg/kg/hr). More than 99% of the drug is protein bound. Volume of distribution is 3L/kg.Brexanolone is metabolized by non-CYP based pathways namely, keto-reduction, glucuronidation, and sulfation. Brexanolone is metabolized into three major circulating metabolites which are pharmacologically inactive. Elimination half life is roughly 9 hours. Drug is majorly excreted through faeces (47%) and urine (42%).

Adverse Reactions:

Most common adverse reactions were (incidence ≥5%) sedation/somnolence, dry mouth, loss of consciousness, and flushing/hot flush. Other reactions reported to Brexanolone include, Drymouth, Diarrhoea, and Oropharyngeal pain.

Contraindications:

- Pregnancy:No adequate clinical data on exposed pregnancies are available for Brexanolone.
- Developmental toxicities were seen in the fetuses of rats and rabbits at 5 and ≥3 times the plasma levels at the maximum recommended human dose (MRHD), respectively.Brexanolone administered to pregnant rats during pregnancy and lactation resulted in lower pup survival and a neurobehavioral deficit in female offspring.
- Lactation:Data from a lactation study in 12 women showed that Brexanolone is transferred to breastmilk in nursing mothers; however, the relative infant dose (RID) is low, 1-2% of the maternal weight-adjusted dosage.Available data do not suggest a significant risk of adverse reactions to breastfed infants from drug exposure

Precautions:

- Brexanolone is associated to cause loss or alteration of consciousness. During the infusion, patients should be monitored for sedative effects every 2 hours. Infusion should be stopped immediately if there are signs or symptoms of excessive sedation. After symptoms resolve, the infusion may be resumed at the same or lower doses. If pulse-oximetry reveals hypoxia, immediately stop the infusion.
- Patients should be cautioned against engaging in potentially hazardous activities requiring mental alertness, such as driving after infusion.

Drug Interactions:

Concomitant use of opioids, antidepressants, or other CNS depressants such as benzodiazepines or alcohol may increase the likelihood/severity of adverse reactions related to sedation.

RECENTLY APPROVED DRUGS BY FDA

S.no	Drug	Active Ingredient	Approval Date	FDA-approved use on approval date
1.	Jeuveau	PrabotulinumtoxinA-xvfs	2/1/2019	For the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.
2.	Cablivi	Caplacizumab-yhdp	2/6/2019	To treat adult patients with acquired thrombotic thrombocytopenic purpura (aTTP).
3.	Egaten	Triclabendazole	2/13/2019	To treat fascioliasis, a parasitic infestation caused by two species of flatworms or trematodes that mainly the affect the liver, sometimes referred to as "liver flukes"
4.	Zulresso	Brexanolone	3/19/2019	To treat postpartum depression (PPD) in adult women.
5.	Sunosi	Solriamfetol	3/20/2019	To treat excessive sleepiness in adult patients with narcolepsy or obstructive sleep apnea.
6.	Mayzent	Siponimod	3/26/2019	To treat adults with relapsing forms of multiple sclerosis.

Available from: Novel Drug Approvals for 2019
https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm592464.htm

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