مركز معلومات الدوية والسموم
Drug & Poison Information Center

Drug & Poison Information Center BULLETIN

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1957
College of Pharmacy
Drug and Poison Information Center

VOLUME 36 ISSUE 3
July–September 2018

Weight loss drug (lorcaserin) shows positive effect on diabetes

Among patients with prediabetes, lorcaserin reduced the risk of diabetes by 19 percent compared to the placebo (172 out of 2,015 patients taking lorcaserin developed diabetes versus 204 out of 1,976 taking the placebo). In addition, 9.2 percent of patients with prediabetes taking lorcaserin were able to achieve normal glycemic levels compared to 7.6 percent of patients taking the placebo (185 out of 2,015 vs. 151 out of 1,976). Lorcaserin also significantly increased the rate of remission of hyperglycemia in patients with diabetes, with 7.1 percent of patients on the drug achieving remission compared to 6 percent of patients on the placebo (242 out of 3,385 vs. 206 out of 3,431).

Source ; *The Lancet*, 2018; DOI: 10.1016/S0140-6736(18)32328-6

In this issue .. ..

Medical News

Diet and Weight may Affect the Response to Bipolar Disorder Treatment – results from clinical trails

Data from a clinical trial has shown that how people respond to treatment for Bipolar Disorder may be influenced by their weight and the overall quality of their diet, including whether they are eating a diet of high in foods thought to contribute to general inflammation.

A total of 133 participants were randomly assigned to take a combination of nutraceuticals (compounds derived from foods such as vitamins or minerals that treat or prevent a disease or disorder) including the anti-inflammatory amino acid n-acetylcysteine (NAC), or NAC alone, or a placebo (a dummy pill) for 16 weeks. Participants received the study medication in addition to any stable treatments they were already receiving. Researchers measured body mass index (BMI) at the beginning of the study, and then measured depression and how a person is able to function in their day to day life. Researchers also rated whether a participant was improving and, if so, how much, over the next 20 weeks. Participants filled in a questionnaire about what they usually eat over the year and researchers calculated a diet quality score, where good diets included a healthy diet with lots of fruit and vegetables, whereas poorer-quality diets had more saturated fat, refined carbohydrates and alcohol.

These types of diets were then categorized as either anti-inflammatory or pro-inflammatory based on foods that affect inflammation.

Study results found that people who had a better-quality diet, a diet with anti-inflammatory properties, or a lower BMI, showed better response to add-on nutraceutical treatment than did those who reported a low-quality diet, or a diet including foods that promote inflammation, or who were overweight. If these results can be repeated in a larger trial, the treatment for bipolar disorder would need to take into account what a person eats and their weight. This is a randomized, controlled trial, but what they found were exploratory outcomes; in other words, it wasn't the main result that they were testing. Their results are statistically significant, but because the study wasn't specifically designed to test the effect of diet quality, inflammatory diets and BMI on drug response in general, it is necessary to see the work replicated in a larger study before any firm conclusions can be formed. In conclusion this is interesting work, which holds out the possibility that patients with bipolar disorder may benefit from a balanced diet. However, it is an early study, and further studies are needed before taking decision that this might affect clinical practice.

Reference; European College of Neuropsychopharmacology. (2018, October 7). Diet and weight may affect response to bipolar disorder treatment. *ScienceDaily*. Retrieved October 14, 2018 from www.sciencedaily.com/releases/2018/10/181007084039.

Community Efforts to Combat Childhood Obesity can be Effective, study finds

A Healthy Communities Study was conducted between 2010 and 2016, and looked at community policies and programs (CPPs) in each of 130 US communities, linking them to the weight status, eating habits and physical activity of 5,138 elementary and middle-school students in those locales. To estimate the dose of CPPs being delivered, the study's researchers devised an intensity score that reflected the number of CPPs in place and their estimated strength, duration and reach.

Analyses were conducted to see whether the intensity of CPPs was associated with lower BMI for children in the communities. The intensity of community programs and policies is significantly associated with lower BMI in children. More comprehensive CPPs those targeting a greater number of distinct behaviors related to physical activity and nutrition were associated with lower child BMI. Community initiatives are more successful when CPPs are in place longer. Across the nation, there's a broad range in the number and intensity of programs and policies aimed at promoting physical activity, healthy nutrition and healthy weight in kids. Some communities invest more in CPPs, others very little. For a community that goes from the minimum observed intensity score to the maximum, its children would see a reduction of -1.4 BMI units. community programs and policies to combat childhood obesity include boosting availability of healthy foods in schools, encouraging kids to drink water instead of sugary beverages, increasing the amount of time that students are physically active, and building walking trails, parks, playgrounds and more pedestrian-friendly neighborhoods.

Resources ; V. L. Collie-Akers et al. he prevalence of community programmes and policies to prevent childhood obesity in a diverse sample of US communities: the Healthy Communities Study ***Pediatric Obesity*, 2018**; DOI: 10.1111/ijpo.12475.

Artificial Sweeteners Have Toxic Effects on Gut Microbes

FDA-approved artificial sweeteners and sport supplements were found to be toxic to digestive gut microbes. Artificial sweeteners have become increasingly controversial due to their questionable influence on consumers health. They are introduced in most foods and many consume this added ingredient without their knowledge. Currently, there is still no consensus regarding the health consequences of artificial sweeteners intake as they have not been fully investigated.

Consumption of artificial sweeteners has been linked with adverse effects such as cancer, weight gain, metabolic disorders, type-2 diabetes and alteration of gut microbiota activity. Moreover, artificial sweeteners have been identified as emerging environmental pollutants, and can be found in receiving waters, i.e., surface waters, groundwater aquifers and drinking waters. In this study, the relative toxicity of six FDA-approved artificial sweeteners (aspartame, sucralose, saccharine, neotame, advantame and acesulfame potassium-k (ace-k)) and that of ten sport supplements containing these artificial sweeteners, were tested using genetically modified bioluminescent bacteria from E. coli. The bioluminescent bacteria, which luminesce when they detect toxicants, act as a sensing model representative of the complex microbial system. Both induced luminescent signals and bacterial growth were measured.

Toxic effects were found when the bacteria were exposed to certain concentrations of the artificial sweeteners. In the bioluminescence activity assay, two toxicity response patterns were observed, namely, the induction and inhibition of the bioluminescent signal. An inhibition response pattern may be observed in the response of sucralose in all the tested strains: TV1061 (MLIC = 1 mg/mL), DPD2544 (MLIC = 50 mg/mL) and DPD2794 (MLIC = 100 mg/mL). It is also observed in neotame in the DPD2544 (MLIC = 2 mg/mL) strain.

On the other hand, the induction response pattern may be observed in its response in saccharin in TV1061 (MLIndC = 5 mg/mL) and DPD2794 (MLIndC = 5 mg/mL) strains, aspartame in DPD2794 (MLIndC = 4 mg/mL) strain, and ace-k in DPD2794 (MLIndC = 10 mg/mL) strain. The results of this study may help in understanding the relative toxicity of artificial sweeteners on E. coli, a sensing model representative of the gut bacteria. Furthermore, the tested bioluminescent bacterial panel can potentially be used for detecting artificial sweeteners in the environment, using a specific mode-of-action pattern.

Reference; Dorin Harpaz, Loo Yeo, Francesca Cecchini, Trish Koon, Ariel Kushmaro, Alfred Tok, Robert Marks, Evgeni Eltzov. **Measuring Artificial Sweeteners Toxicity Using a Bioluminescent Bacterial Panel**. *Molecules*, 2018; 23 (10): 2454 DOI: 10.3390/molecules23102454.

Patients with Diabetes were More Likely to Have Arthritis and Osteoporosis- data from National Health Survey

A study that draws on data from more than 100,000 people finds a link between diabetes and an increased risk of osteoporosis, osteoarthritis, and rheumatoid arthritis. In the United States, over 100 million people are living with diabetes and prediabetes. Type 2 diabetes is a chronic condition requiring lifelong management; the disease impacts a number of systems in the body.

The results were presented at the European Association for the Study of Diabetes Annual Meeting, held in Berlin, Germany. In order to investigate, the scientists took data from the 2013 Danish National Health Survey; in all, they had access to the records of 109,218 people aged 40 or older. Of these people, 8.5 percent were diagnosed with diabetes; also, they were more likely to be male, older, and have a higher body mass index. (BMI).

Once the investigators had controlled for risk factors, such as age, gender, and BMI, a significant pattern still emerged. They found that people with diabetes were 33 percent more likely to have osteoarthritis; they were also more likely to have rheumatoid arthritis and osteoporosis (the risk increased by 70 percent and 29 percent, respectively).

Aside from these specific conditions, when compared with people without diabetes, those with diabetes were 27 percent more likely to report back pain and 29 percent more likely to have shoulder and neck pain. The particularly pronounced relationship between rheumatoid arthritis and diabetes could be due to the presence of chronic inflammation in both conditions. While use of steroids in the treatment of [rheumatoid arthritis also increase the risk of the development of type 2 diabetes.

The researchers demonstrated that people with diabetes who were more active had a reduced risk of back, shoulder, and neck pain. The researchers hope that their findings might help physicians guide their patients. Healthcare professionals should make patients with diabetes aware that regular exercise is a recognized treatment for diabetes and arthritis, and can have positive effects on both blood sugar control as well as musculoskeletal pain. It is important to note that this study was observational, so cause and effect cannot be picked apart. There may be risk factors that these conditions share that we do not yet understand. Also, as the authors explain, the data they used are based on participants' self-reports, which makes them considerably less reliable.

Source; https://www.medicalnewstoday.com.

SGLT2 (sodium-glucose cotransporter-2) Inhibitors for Diabetes: Drug Safety Communication Regarding Rare Occurrences of a Serious Infection of the Genital Area.

The U.S. Food and Drug Administration (FDA) is warning that cases of a rare but serious infection of the genitals and area around the genitals have been reported with the class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. We are requiring a new warning about this risk to be added to the prescribing information of all SGLT2 inhibitors and to the patient Medication Guide.

SGLT2 inhibitors are FDA-approved for use with diet and exercise to lower blood sugar in adults with type 2 diabetes. SGLT2 inhibitors lower blood sugar by causing the kidneys to remove sugar from the body through the urine. First approved in 2013, medicines in the SGLT2 inhibitor class include canagliflozin, dapagliflozin, empagliflozin, and ertugliflozin. In addition, empagliflozin is approved to lower the risk of death from heart attack and stroke in adults with type 2 diabetes and heart disease. Untreated, type 2 diabetes can lead to serious problems, including blindness, nerve and kidney damage, and heart disease. **Patients** should **seek medical attention immediately** if you experience any symptoms of tenderness, redness, or swelling of the genitals or the area from the genitals back to the rectum, and have a fever above 100.4 F or a general feeling of being unwell. These symptoms can worsen quickly, so it is important to seek treatment right away.

Health care professionals should assess patients for Fournier's gangrene if they present with the symptoms described above. If suspected, start treatment immediately with broad-spectrum antibiotics and surgical debridement if necessary.

Discontinue the SGLT2 inhibitor, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control. The bacteria usually get into the body through a cut or break in the skin, where they quickly spread and destroy the tissue they infect. Having diabetes is a risk factor for developing Fournier's gangrene; however, this condition is still rare among diabetic patients. Overall published literature about the occurrence of Fournier's gangrene for men and women is very limited. Publications report that Fournier's gangrene occurs in 1.6 out of 100,000 males annually in the U.S., and most frequently occurs in males 50-79 years (3.3 out of 100,000).[1-3] In our case series, however, we observed events in both women and men.

In 2017, an estimated 1.7 million patients received a dispensed prescription for an SGLT2 inhibitor from U.S. outpatient retail pharmacies.[7] Although most cases of Fournier's gangrene have previously been reported in men, our 12 cases included 7 men and 5 women. Fournier's gangrene developed within several months of the patients starting an SGLT2 inhibitor and the drug was stopped in most cases. All 12 patients were hospitalized and required surgery. Some patients required multiple disfiguring surgeries, some developed complications, and one patient died. In comparison, only six cases of Fournier's gangrene (all in men) were identified in review of other antidiabetic drug classes over a period of more than 30 years.

Source; https://www.fda.gov/Safety/MedWatch/SafetyInformation.

Medication Safety Updates

FDA Approves Xyosted (testosterone enanthate) Injection for Testosterone Replacement Therapy in Adult Males

Antares Pharma Inc. announced the approval of Xyosted (testosterone enanthate) injection by the U.S. Food and Drug Administration (FDA). Xyosted is the first FDA approved subcutaneous testosterone enanthate product for once-weekly, at-home self-administration with an easy-to-use, single dose, disposable QuickShot® auto injector. Xyosted has been approved in three dosage strengths, 50 mg, 75 mg and 100 mg and is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Published data from the Xyosted phase three studies have shown that product to be easy to use and virtually pain free while providing steady testosterone levels. Xyosted can cause blood pressure increases that can increase the risk for major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death, with greater risk for MACE in patients with cardiovascular risk factors or established cardiovascular disease.

Source; https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm592464.htm.

FDA Approves Ajovy (fremanezumab-vfrm) for Preventive Treatment of Migraine

The US Food and Drug Administration (FDA) approved Ajovy (fremanezumab-vfrm) for the preventive treatment of migraine in adults. Ajovy is the second FDA-approved preventive migraine treatment in a new class of drugs that work by blocking the activity of calcitonin gene-related peptide (CGRP), a molecule that is involved in migraine attacks. Migraine headache pain as an intense pulsing or throbbing pain in one area of the head. Additional symptoms include nausea and/or vomiting and sensitivity to light and sound. Migraine attacks can cause significant pain or hours to days and can be so severe that the pain is disabling.

Ajovy is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients. Hypersensitivity reactions, including rash, pruritis (itching), drug hypersensitivity, and urticaria (hives) were reported with Ajovy in clinical trials. Most reactions were mild to moderate, but some led to discontinuation or required corticosteroid treatment. Most reactions were reported from within hours to one month after administration. The most common adverse reactions were injection site reactions and infections.

***Source**; https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm592464.htm.*

"الغذاء والدواء" تسحب احترازياً مستحضرات لعلاج ارتفاع ضغط الدم بسبب وجود شوائب في المادة الفعّالة

1439/10/26

عمّمت الهيئة العامة للغذاء والدواء على الجهات الصحية كافة لسحب عدد من المستحضرات التي تستخدم لعلاج ارتفاع ضغط الدم وفشل القلب، إثر تقارير تفيد بوجود شوائب متمثلة بمادة N-Nitrosodimethylamine (NDMA) التي قد تكون مادة مسرطنة ضمن مكونات المادة الفعالة Valsartan التي يتم توريدها من المصدر التالي:

Zhejiang Huahai Pharmaceuticals in Linhai, China.

وتبين للهيئة بعد مراجعة سجلاتها وجود عدد من المستحضرات التي يتم إنتاجها باستخدام المادة الفعالة من ذلك المصدر.

ولفتت الهيئة إلى أن سحب تلك المستحضرات إجراء احترازي لحين اكتمال إجراءات التحقق من نسبة تركيز هذه الشوائب وأثر وجودها على مستخدمي الدواء، مشيرة إلى أن هناك بدائل مسجلة لنفس المادة العلاجية Valsartan تتوفر من مصادر تصنيعية أخرى لم تتأثر بهذه المادة، ويجب مراجعة الطبيب المعالج أو الصيدلي لمعرفة تلك البدائل.

المصدر: *الهيئة العامة للغذاء و الدواء*

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

	اسم المستحضر	صورة المستحضر	رقم التسجيل	الشركة الصانعة
1	VALISTA 80 mg film-coated tablet		311-212-14	ACTAVIS
2	VALISTA 160 mg film-coated tablet		312-212-14	ACTAVIS
2	VALISTA 320 mg film-coated tablet		313-212-14	ACTAVIS
4	CO-VALISTA 80/12.5 mg film-coated tablet		314-212-14	ACTAVIS
5	CO-VALISTA 160/12.5 mg film-coated tablet		315-212-14	ACTAVIS
6	CO-VALISTA 160/25 mg film-coated tablet		316-212-14	ACTAVIS
7	CO-VALISTA 320/12.5 mg film-coated tablet		317-212-14	ACTAVIS
8	CO-VALISTA 320/25 mg film-coated tablet		318-212-14	ACTAVIS
9	DIOSTAR 80 mg film-coated tablet		45-399-15	Pharma International Co.
10	DIOSTAR 160 mg film-coated tablet		46-399-15	Pharma International Co.
11	DIOSTAR PLUS 80/12.5 mg film-coated tablet		47-399-17	Pharma International Co.
12	DIOSTAR PLUS 160/12.5 mg film-coated tablet		48-399-17	Pharma International Co.
13	DIOSTAR PLUS 160/25 mg film-coated tablet		49-399-17	Pharma International Co.

"الغذاء والدواء" تعلّق تسجيل مستحضرين لعلاج السكري لعدم تكافؤهما حيوياً"

1439/11/5

علّقت الهيئة العامة للغذاء والدواء تسجيل مستحضر Glymide 5mg Tablet ومستحضر Diatab 5mg Tablet لعدم تكافؤهما حيوياً مع المستحضر المرجعي. وخاطبت الهيئة الجهات الصحية لسحب المستحضرين في حال وجودهما لديها، كما خاطبت وكيلي المستحضرين لسحبهما من جميع الجهات المستفيدة، لكافة التشغيلات. ويحمل المستحضر الذي تصنعه"شركة جلفار" الاسم التجاري Glymide 5mg Tablet والاسم العلمي Glibenclamide ورقم التسجيل 279-186-10، والمستحضر الذي تصنعه "شركة سبيماكو الدوائية" الاسم التجاري Diatab 5mg Tablet والاسم العلمي Glibenclamide ورقم التسجيل 16-212-94. وجاء تعميم الهيئة بناءً على قرار لجنة تسجيل شركات ومصانع الأدوية ومنتجاتها بالهيئة رقم 42/952/sfda/39 والقرار رقم 41/952/sfda/39 القاضي بتعليق تسجيل المستحضر، مشيرة إلى أن هناك بدائل مسجلة للمادة العلاجية نفسها، ويجب مراجعة الطبيب المعالج أو الصيدلي لمعرفة تلك البدائل.

وأهابت بالمستهلكين إبلاغ المركز الوطني للتيقظ والسلامة الدوائية عند حدوث أي أعراض جانبية للأدوية عن طريق :

الرقم المجاني: ٨٠٠٢٤٩٠٠٠٠

أو الفاكس: ٠٠٩٦٦١١٢٠٥٧٦٦٢

أو الرقم الموحد: 19999

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أو الرابط https://ade.sfda.gov.sa

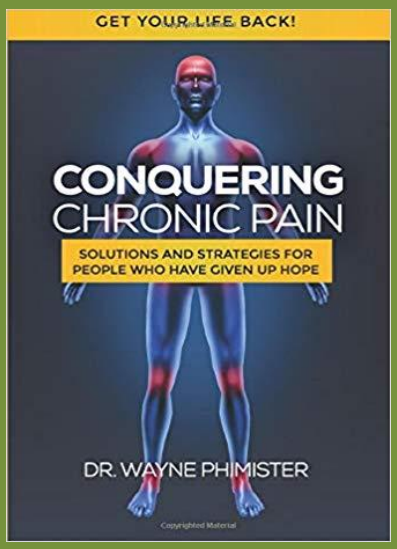
المصدر: *الهيئة العامة للغذاء و الدواء*

Scientific Books: New Release

Conquering Chronic Pain: Solutions and Strategies for People Who Have Given up Hope Paperback

Dr. Wayne Phimister (Author)

Conquering Chronic Pain; Solutions and Strategies for People Who Have Given up Hope is a must-read for anyone suffering from chronic pain. It's an encouraging and enlightening guide to pain relief options, including non-traditional and unexpected treatments, and it demonstrates how a person's mindset and attitude can be more beneficial than any medication. Dr. Wayne Phimister interviews medical and health professionals, experts and educators, and gets them to share information and insights that will be valuable to anyone suffering any type of chronic pain.



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Upcoming Conferences

- November 05-07, 2018; 18th Annual Pharma Middle East Congress Abu Dhabi, UAE. Theme: Innovate the Excellence in Pharma Sciences
- November 15-16, 2018; 9th Global Experts Meeting on Neuropharmacology. Theme: Neuropharmacology: Major Challenges and Breakthroughs. Berlin, Germany
- December 10-11, 2018. 23rd International Conference on Pharmaceutical Biotechnology. Theme: Shaping the Future with Latest Advancements in Pharmaceutical Biotechnology Rome, Italy.
- December 10-11, 2018. 10th Annual Congress on Drug Formulation & Analytical Techniques. Dubai,

Editorial Board

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ISSN: 1319 – 43021319 – 4302 :ردمد