مركز معلومات الدوية والسموم
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Drug discovery: A potential new treatment for malaria

In a search for novel antimalarial agents, researchers discovered a compound (DDD107498) that is effective against multiple life-cycle stages of the parasite. DDD107498 works by blocking protein synthesis in P. falciparum and achieves this effect by inhibiting a gene that encodes PfeEF2, which regulates protein production. Thus, PfeEF2 represents a newly identified drug target in malaria that may aid drug discovery.

Source: Medical news today

In this issue .. ..

Medical News

Current BMI tests underestimate obesity in teens with disabilities

New approaches, based on body mass index (BMI) or other simple measures, are needed to improve assessment of obesity in adolescents with physical disabilities, reports a paper in the *American Journal of Physical Medicine & Rehabilitation*, the official journal of the Association of Academic Physiatrists.

Obesity is a major problem in children and adolescents with mobility limitations, but standard assessments tend to underestimate it, according to the new research by Brooks C. Wingo, PhD, of University of Alabama at Birmingham and colleagues. They suggest new cutoff points are needed for identifying disabled teens who may need diagnosis and treatment to prevent health and functional problems due to excess body weight.

What's the Best Measure to Assess Obesity in Disabled Teens?

The study included 29 adolescents (average age 16) who had spinal cord injury or other types of physical disability and used a wheelchair to get around. The researchers assessed various clinical indicators of body weight--not only BMI (calculated from height and weight), but also the width of a skinfold pinched in the upper arm (triceps) and circumferences of the waist, arm, and leg.

In addition, a procedure called dual-energy X-ray absorptiometry (DXA) was done to measure the patients' percentage of body fat. Obesity was defined as 30 percent or greater body fat for males and 35 percent or greater for females. The various clinical measures were evaluated as indicators of obesity, as objectively determined by DXA.As in previous studies; many of the teens with physical disability were obese. Thirty-five percent of boys and 58 percent of girls met the DXA criteria points for obesity. However, if assessed by BMI alone, many of the patients would be misclassified as non-obese. Based on the standard BMI cutoff point of 95th percentile or higher for their age, only six percent of boys and 42 percent of girls were classified as obese.

All of the clinical measures were significantly correlated with body fat among the teens with disabilities. The best-performing measure was BMI, using a cutoff point of 20 for boys and 19 for girls. The second-best measure was waist circumference, with cutoff points of 83 centimeters (about 33 inches) for boys and 78 centimeters (about 31 inches) for girls. Children and adolescents with physical disabilities are at high risk for obesity. In addition to health issues such as diabetes and heart disease, obesity puts disabled youth at risk of a wide range of other problems, such as pain and depression, and may further limit their independence and mobility.

But it can be challenging to assess obesity and overweight in people with disabilities, and especially in children and adolescents. While DXA is a more reliable test for measuring body fat, it's not practical for everyday clinical use. The exploratory study confirms that current cutoff points underestimate obesity in adolescents with physical disabilities. It also provides a first step toward developing alternative assessments of obesity in this group of patients, although further research will be needed to confirm and validate the proposed alternative measures. Dr. Wingo and coauthors also call for the development of disability-specific cutoff points, "which will allow clinicians to better identify children at risk of adiposity-related diseases and offer parents preventive strategies to improve the health and quality of life of their children."

Source: U.S. Food and Drug Administration

Call for help to killer cells improves cancer rejection

Summary: Many tumors are infiltrated by cells of the innate immune system called eosinophils. Immunologists are now the first to show that eosinophils do, in fact, improve the body's defense against cancer. By releasing special agents, they attract killer T cells into cancerous tissue; the T cells then attack the cancer cells. This finding may help develop more effective cancer immunotherapies.

Sometimes it takes a long time to solve a puzzle: In 1893, German surgeon G. Reinbach discovered that tumor tissue is often infiltrated by special cells of the immune system called eosinophils. Ever since then, scientists have been trying to figure out if and how these cells, which are part of the innate immune system, are involved in cancer rejection.

There are many studies that link the presence of eosinophils in a tumor with an improved prognosis of the disease. However, even 120 years after Reinbach's discovery, it still remained elusive whether or not eosinophils actively play a role in fighting the tumor," says Prof. Günter Hämmerling from the German Cancer Research Center (Deutsches Krebsforschungszentrum, DKFZ).

Immunologist Hammering hypothesized that tumor eosinophils might act as mediators that call for help to other immune cells, thus initiating an immune defense against the tumor. Most prior studies had not taken into account the involvement of other components of the immune system.

Dr. Rafael Carretero from Hämmerling's department has now been able to confirm this hypothesis. Carretero discovered that eosinophils release special agents that attract the immune system's "professional killers" into cancer tissue. These immune cells, called CD8+ T cells, then go ahead and attack the tumor.

Mice whose eosinophils had been incapacitated using antibodies exhibited poor defense mechanisms against tumors and soon succumbed to the disease. In these animals, strikingly low quantities of CD8+ T cells infiltrated the tumor. Carretero also showed that the agents released by the eosinophils are, in fact, responsible for attracting the T cells. To prove this, he used antibodies to catch these attractants. Under these circumstances, hardly any T cells invaded the tumor. Nor was it possible to attract T cells into the tumor when the researchers transplanted non-activated eosinophils, which do not produce attractants, into the mice.

An important approach in advanced cancer medicine is to treat cancer using a patient's immune cells after first arming the cells against the tumor in culture. However, these therapies often fail because insufficient numbers of T cells reach the tumor. Carretero and his colleagues therefore investigated whether the outcomes of these immunotherapies might be improved by adding eosinophils.

While transplantation of T cells alone had only little impact on tumor size in cancerous mice, the researchers achieved substantial regression of the cancer by transplanting both T cells and activated eosinophils. Mice that had received this combination survived significantly longer than animals in the control group that had received only T cells. In subsequent experiments, the investigators showed that eosinophils alone -- in the absence of T cells -- fail to improve cancer rejection.

Apart from their call for help to killer cells, eosinophils had another impact on the immediate environment of a tumor. They normalized blood vessels in the tumor, thus additionally contributing to tumor rejection.

"We have solved a 100-year-old puzzle here and we have shown that eosinophils initiate cancer rejection by sending out a molecular call for help," says Hämmerling, the study head. He adds: "This knowledge will enable us to significantly enhance cellular immunotherapies by guiding more T cells into a tumor." His team is currently studying cases in which cancer patients have been treated by immunotherapy. The researchers want to find out if and how higher levels of eosinophils correlate with better treatment outcomes.

Source : Rafael Carretero, Ibrahim M Sektioglu, Natalio Garbi, Oscar C Salgado, Philipp Beckhove, Günter J Hämmerling. *Eosinophils orchestrate cancer rejection by normalizing tumor vessels and enhancing infiltration of CD8 T cells.* **Nature Immunology,** ***2015; 16 (6): 609 DOI:10.1038/ni.3159***

FDA approves Rapamune to treat LAM, a very rare lung disease

May 28, 2015

The U.S. Food and Drug Administration today approved Rapamune (sirolimus), to treat lymphangioleiomyomatosis (LAM), a rare, progressive lung disease that primarily affects women of childbearing age. This is the first drug approved to treat the disease. LAM is characterized by an abnormal growth of smooth muscle cells that invade lung tissues, including the airways, and blood/lymph vessels that cause destruction of the lung, resulting in airflow obstruction, and limiting the delivery of oxygen to the body. LAM is a very rare disease. According to the U.S. National Library of Medicine, only between two and five women per million women worldwide are known to have the disease.

The safety and efficacy of Rapamune for treatment of LAM were studied in a clinical trial that compared Rapamune with an inactive drug (placebo) in 89 patients for a 12-month treatment period, followed by a 12-month observation period. The primary endpoint was the difference between the groups in the rate of change in how much air a person can exhale during a forced breath in one second (forced expiratory volume in one second or FEV1). The difference in the average decrease in FEV1 during the 12-month treatment period was approximately 153 mL. After discontinuation of Rapamune, the decline in lung function resumed at a rate similar to the placebo group.The most commonly reported side effects associated with Rapamune for the treatment of LAM were mouth and lip ulcers, diarrhea, abdominal pain, nausea, sore throat, acne, chest pain, leg swelling, upper respiratory tract infection, headache, dizziness, muscle pain and elevated cholesterol. Serious side effects including hypersensitivity and swelling (edema) have been observed in renal transplant patients.

Source: U.S. Food and Drug Administration

FDA approves brain implant to help reduce Parkinson's disease and essential tremor symptoms

June 12, 2015 : The U.S. Food and Drug Administration today approved the Brio Neurostimulation System, an implantable deep brain stimulation device to help reduce the symptoms of Parkinson's disease and essential tremor, a movement disorder that is one of the most common causes of tremors. The Brio Neurostimulation System can help some patients when medication alone may not provide adequate relief from symptoms such as walking difficulties, balance problems, and tremors. Data supporting the safety and effectiveness of the device system included two clinical studies. One study included 136 patients with Parkinson's disease and the other included 127 patients with essential tremor. In both studies, patients had symptoms, including tremors, that were not adequately controlled with drug therapy.

The Brio Neurostimulation System was used in addition to medication for patients with Parkinson's disease and the majority of patients with essential tremor who used the device were able to control their symptoms without the need for medications. Researchers implanted the Brio Neurostimulation System in all patients and assessed effectiveness for Parkinson's disease patients at three months and essential tremor patients at six months. Both groups showed statistically significant improvement on their primary effectiveness endpoint when the device was turned on compared to when it was turned off. Brio Neurostimulation System is the second device approved by the FDA for Parkinson's and essential tremor. The first device, Medtronic's Activa Deep Brain Stimulation Therapy System, was approved in 1997 for tremor associated with essential tremor and Parkinson's disease. In 2002, the indications were expanded to include the symptoms of Parkinson's disease.
Source: ***U.S. Food and Drug Administration***

Unintentional Injection of Soft Tissue Filler into Blood Vessels in the Face: FDA Safety Communication

***Product*:**

Soft tissue fillers, also called dermal fillers, injectable facial implants, or wrinkle fillers, can create a smoother or fuller appearance of the face. They are FDA-approved to reduce the appearance of wrinkles or to augment lips or cheeks. Soft tissue fillers are injected directly into a treatment area. Successful results will depend on the patient's overall health and skin condition, the skill of the health care provider, the location of injection and the type of filler used. Patients may need more than one injection to get the desirable smoothing/filling effect. Soft tissue fillers should be injected only by health care providers who have appropriate training and experience and who are knowledgeable about the anatomy at and around the injection site.

Purpose

The FDA is alerting health care providers and consumers about the possibility of rare, but serious, injuries that may occur due to unintentional injection of soft tissue filler into blood vessels in the face

Summary of Problem and Scope

The FDA has reviewed information that suggests unintentional injection of soft tissue fillers into blood vessels in the face can result in rare, but serious side effects. Unintentional injection can block blood vessels and restrict blood supply to tissues. Sometimes this can result in embolization. This means the filler material has traveled to other parts of the body. This can cause vision impairment, blindness, stroke and damage and/or death of the skin (necrosis) and underlying facial structures. While unintentional injections into blood vessels may occur with injection sites anywhere on the face, the FDA's review of literature and adverse event reports submitted to the FDA identifies certain injection locations where blood vessel blockage have been reported more often These sites include the skin between the eyebrows and nose (glabella), in and around the nose, forehead, and around the eyes(periorbital region).

Recommendations for Health Care Providers

Do not inject soft tissue fillers if you do not have the appropriate training or experience. Make sure that you are familiar with the anatomy at and around the site of injection, keeping in mind that blood vessel anatomy can vary among patients. Before injection, thoroughly inform the patient of all risks of the procedure and the specific product you intend to use. Note that the approved indications for use of soft tissue fillers vary depending on the product. The FDA may not have reviewed use of soft tissue fillers in some locations in the body.

Take extra care when injecting soft tissue fillers, for example inject the product slowly and apply the least amount of pressure necessary. Know the signs and symptoms associated with injection into blood vessels, and have an updated plan detailing how you plan to treat the patient if this should this occur. This may include on-site treatment and/or immediate referral to another health care provider for treatment. Immediately stop the injection if a patient exhibits any signs or symptoms associated with injection into a blood vessel, such as changes in vision, signs of a stroke, white appearance (or blanching) of the skin, or unusual pain during or shortly after the procedure. Tell patients that they should seek immediate medical attention after the procedure if they experience signs and symptoms associated with injection into a blood vessel

Educate health care facility employees on how to quickly assist patients that report signs and symptoms of filler complications. They must understand how to instruct the patient to receive appropriate medical care. Report to the FDA and the manufacturer if you become aware of a patient experiencing an adverse event associated with unintentional injection of soft tissue filler into a blood vessel.

Recommendations for Consumers:

Before deciding to have soft tissue filler injections, talk with your health care provider about appropriate treatment injection sites and the risks associated with the procedure. Be aware that FDA reviewed and approved different products for use in certain areas of the face. The FDA may not have reviewed the use of certain soft tissue fillers for all locations in the body.

Read and discuss the patient labeling for the specific filler you are receiving. Your doctor can provide this information, or you can find it on the FDA's website

Ask your health care provider about their training and experience injecting soft tissue fillers in the face.

Seek immediate medical attention if you develop symptoms such as unusual pain, vision changes, a white appearance of skin near the injection site, or any signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion) during or shortly after the procedure.

FDA Actions

After reviewing additional information on this subject, the FDA is working with manufacturers to update their labeling. The requests asks that the labeling include additional warnings, precautions, and other statements about the risk of unintentional injection into blood vessels, consistent with the recommendations in this communication, so that both health care providers and patients would have a better understanding of the risks.

The FDA continuously monitors reports of injuries caused by soft tissue fillers. With the increased popularity of soft tissue fillers, more information is available about unintentional injection into blood vessels. While current labeling includes some information about this risk, the FDA believes that additional information can be included in the labeling to better inform health care providers and patients.

Reporting Problems to the FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with these products. If you suspect or experience a problem with soft tissue fillers, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Source: U.S. Food and Drug Administration

بيان من "الغذاء والدواء": لا خلل في شراب بانادول للرضع والأطفال بالسعودية

1436/07/27

إشارة إلى ما نشرته بعض الصحف والمواقع الإخبارية في عدة دول خليجية، بخصوص سحب جميع تشغيلات مستحضر (بانادول شراب الرضع والأطفال) من أسواقها، بناء على طلب الشركة المنتجة، بسبب اكتشاف خطأ في تحديد نسبة الجرعات المدونة على عبوة الدواء الخارجية، تود الهيئة العامة للغذاء والدواء، أن توضح للمستهلكين، أن المستحضر (PANADOL BABY & INFANT SUSP 120MG-5ML) رقم تسجيل 1-309-98 عن طريق الشركة المسوقة (GLAXOSMITHKLINE (GSK ، مسجل في السوق السعودي ، ولا يوجد فيه خلل . وخاطبت الهيئة العامة للغذاء والدواء الشركة المسوقة، وطلبت تقريراً مفصلاً يبين مدى تأثر السوق السعودي وأوضحت الشركة عدم تأثر السوق السعودي.

دراسة لـ"الغذاء والدواء": "البيسفينول أ" في الأغذية والمشروبات ورضّاعات الأطفال بالسعودية لا يتجاوز الحد المسموح به

1436/08/02

أجرت الهيئة العامة للغذاء والدواء، دراسة لرصد متبقيات مركّب "البيسفينول أ" في بعض المشروبات المعلبة والمياه المعبأة والأغذية ورضّاعات الأطفال، توصلت إلى أن مستوى المركّب متدنية في جميع العينات. ويمكن أن ينتقل "البيسفينول أ" من مواد التعبئة والتغليف (عبوات عديد الكربونات أو العبوات المعدنية) إلى الغذاء وبالتالي إلى جسم الإنسان فيؤثر سلباً على الهرمونات الجنسية إذا زاد التركيز عن الحدود المسموح بها. وتضمنت الدراسة التي أجرتها الهيئة العامة للغذاء والدواء، سحب عينات عشوائية من الأسواق المحلية بمدينة الرياض للتأكد من أن مستويات "البيسفينول أ" إن وجدت لا تتجاوز الحد الأعلى المسموح به في هذه المنتجات وهو الحد الآمن للمستهلك، المعتمد من قبل الهيئات الدولية المتخصصة، وشملت الدراسة جمع وتحليل ١٣٠ عينة، هي ٦٦ عينة مشروبات معلبة، و٣٠ عينة مياه معبأة، و١٣ عينة زيوت معلبة، و٩ عينات تونا معلبة، و١٢ عينة من رضاعات الأطفال. وأظهرت نتائج تحليل العينات تدني مستوى "البيسفينول أ" في جميع العينات المسحوبة (١١٨ عينة غذائية، ١٢ عينة رضاعات أطفال)، إذ كانت نتائج العينات أقل من الحد المسموح به بكثير. ويوجد بدائل لعلب رضاعات الأطفال المصنعة من مادة عديد الكربونات المحتوية على "البيسفينول أ" مثل الزجاج والبولي بروبيلين (PP) وهي مواد لا يدخل في تصنيعها مركب "البيسفينول أ."

"الغذاء والدواء": سحب مستحضرات تحتوي"pregabalin" من الصيدليات بشكل عاجل

1436/08/11

شددت الهيئة العامة للغذاء والدواء الرقابة على صرف المستحضرات التي تحتوي على عقار"pregabalin" عقب ورود بلاغات تشير إلى وجود حالات إساءة استخدام لهذه المستحضرات، قد ينتج عنها أعراض جانبية خطيرة. وقررت "الهيئة" في تعميمها سحب هذه المستحضرات من الصيدليات الخاصة بشكل عاجل، إضافة الى قصر استخدام هذه المستحضرات على المستشفيات الحكومية والخاصة ومراكز الرعاية الصحية الأولية الحكومية، مع حصر صلاحية وصف هذه المستحضرات.

لإنقاص الوزن (AB Slim) الغذاء والدواء" تحذر من مستحضر"

1436/08/15

حذرت الهيئة العامة للغذاء والدواء المستهلكين من مستحضر على شكل كبسولات يحمل اسم(AB Slim) لأنه يروج على أنه مستحضر طبيعي لإنقاص الوزن، في حين أن هذا الادعاء مضلل وليس له أي أساس من الصحة.

المصدر: *الهيئة العامة للغذاء والدواء*

Scientific Books: New Release

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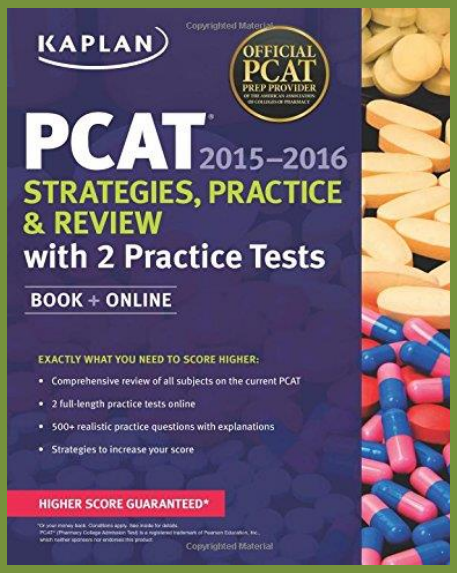

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Upcoming Conferences

- 25th - 26th June 2015 .The European Clinical Trial Directive-Plus-European Filings and Registration Procedures at the Tampa, FL in Tampa, FL, USA .
- 1st - 3rd July 2015 RICT Drug Discovery and Selection Understanding Targets and Mechanisms. At the University d'Avignon et des Pays de Vaucluse in Avignon, France
- 13th - 15th July 2015 International Conference on Eye Disorders and Treatment at the Double Tree Hilton BWI Airport, Baltimore in Baltimore, Maryland, USA.
- 20th - 22nd July 2015 World Congress on Pharmacology at the 190 ELIZABETH STREET, BRISBANE, QUEENSLAND, 4000, AUSTRALIA

Editorial Board

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