مركز معلومات الدوية والسموم
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High frequency stimulation in pain medicine

Due to disease-related changes in their brain, pain patients often suffer from an impaired tactile ability in their hands. In a pilot study conducted by scientists high frequency repetitive stimulation was investigated as a therapeutic approach for these patients. The results of this study show that passive stimulation of this kind is a promising new therapy option.

Source: Sciencedaily.com

In this issue .. ..

Medical News

Acetaminophen is "an ineffective treatment for osteoarthritis": results from a *large-scale meta-analysis*

Large scale meta-analysis concludes that acetaminophen alone not effective at any dose" for relieving pain or improving physical function for patients with osteoarthritis, Furthermore, Researchers found that non-steroidal anti-inflammatory drug (NSAID) diclofenac in particularly was most effective agent for short-term pain relief from osteoarthritis, even though the authors recommend against taking the medication long term due to its side effects.

Osteoarthritis is the most common form of arthritis, affecting an estimated 27 million Americans aged 25 and older, primarily those who are over the age of 65.

In osteoarthritis, the cartilage of the joints - the connective tissue that covers the end of the bones, acts as a cushion - breaks down, allowing the bones to rub together. This causes inflammation, stiffness and pain. The hands, spine, knees and hips are the joints most commonly affected by osteoarthritis.

Acetaminophen and NSAIDs are considered the first-line treatment for relieving mild-to-moderate pain among patients with the osteoarthritis, however Dr. Trelle and colleagues note that acetaminophen is more widely used in the long term therapy because it poses fewer side effects than NSAIDs.

In their study, the researchers set out to determine which medications are most effective for treating osteoarthritis pain.

Acetaminophen 'showed no clinically important difference' The researchers analyzed the data of 74 randomized trials conducted between 1980-2015 that included 58,556 patients with osteoarthritis.

Medical News (cont..)

Overall, the studies compared the effects of 22 different medications - including acetaminophen and seven different classes of NSAIDs - against a placebo to assess how they affected patients' pain intensity and physical function at various doses.

All medications at all doses were found to have beneficial effects in comparison with a placebo.

However, while some doses of paracetamol offered a slight improvement in pain intensity and physical function for patients, the effect did not reach the minimum standards of clinical effectiveness defined as the smallest change in a treatment outcome that a patient would deem important.

In this study, the clinically important difference was -0.37, while treatment with acetaminophen only reached -0.17. The NSAID diclofenac at a dose of 150 mg daily, was found to be most effective for reducing pain intensity and improving physical function, with a clinically important difference of -0.57. This effect was greater than that offered by maximum doses of other NSAIDs commonly used for the treatment of osteoarthritis, including ibuprofen, celecoxib and naproxen.

NSAIDs are usually only used to treat short-term episodes of pain in osteoarthritis, because their side effects are thought to outweigh the benefits when used for longer term.as result, paracetamol is often prescribed to manage the long-term pain instead of NSAIDs.

However, results suggest that paracetamol at any dose is not effective in managing pain in osteoarthritis, but certain NSAIDs are effective and can be used intermittently without paracetamol.

Patients may be 'suffering needlessly'

Results of the previous study , notes that there were a number of NSAIDs commonly used for the treatment of osteoarthritis that were not included in the meta-analysis, possibly because there have been no recent trials of such drugs or the trials that have been conducted are too small.

"These omissions are unfortunate because these drugs might be as effective as but much cheaper than the newest drugs, author of the study believes the finding that acetaminophen is ineffective for the treatment of osteoarthritis is "remarkable," though perhaps unsurprising.

“Paracetamol has been on the market for as long as most of us remember. Its efficacy has never been properly established or quantified in chronic diseases, and is probably not as great as many would believe. Its safety is also questioned, not just in overdose,"

"Many patients could be suffering needlessly because of perceived NSAIDs risks and paracetamol benefits (which might not be real). Perhaps researchers need to reassess both these perceptions (and misconceptions) and the use of other analgesic options that have been discarded over time, such as dipyrone."

Source: Written by Honor Whiteman

A study of Implantable capsule shows a promise for Alzheimer's prevention

Currently there is no way to prevent r slow Alzheimer's disease, but a new study details the creation of an implantable capsule that researchers say could stop the condition in its tracks. Beta-amyloid protein is believed to be a key player in the development of Alzheimer's disease. The protein clumps together in the brain, forming plaques that accumulate in the spaces between nerve cells interfere with the processes these cells need to survive.

Scientists have been searching for ways to tackle these plaques, and one idea is to "tag" beta-amyloid proteins with antibodies released by immune system to attack and destroy them before they can form plaques.

However, the researchers of this latest study note that such treatment has to be administered in the early stages of cognitive decline to be most effective. This requires repeat injections which can lead to adverse side effects.

How does the implantable capsule work?

The capsule, described as a "microencapsulation device," is 27 mm in length, 12 mm wide and 1.2 mm thick. It consists of cells taken from muscle tissue that have been genetically engineered to produce high levels of antibodies that have the ability to recognize and target beta-amyloid proteins in the brain.

When implanted in tissue under the skin, the capsule gradually releases the antibodies into the bloodstream. These antibodies released by the capsules, cross from the blood to the brain to seek out and tag beta-amyloid protein, which triggers an immune system attack**.** The researchers notes that these genetically engineered cells not only release antibodies, but in order to avoid rejection from the immune system, they must be compatible with the patient. As such, the cells are surrounded by two permeable membranes - fixed together by polypropylene frame that not only protect them against immune system attack, but enable cells from a single donor to be used on multiple patients. Furthermore, the permeable membranes allow the cells to soak up all the nutrients and molecules they need from surrounding tissue.

Alzheimer's mice showed reduction in beta-amyloid plaques

This experiment was conducted to testify the implantable capsule on mouse models of early Alzheimer's disease and assessed them for around 39 weeks**.** The results found a significant reduction in levels of beta-amyloid protein and plaques suggesting that the continuous flow of antibodies produced by the capsule over the 39-week period prevented the plaques from forming**.** Additionally, the team found that the mice demonstrated lower phosphorylation of a protein called tau, which is also believed to play a role in Alzheimer's development by forming "tangles" that build up inside nerve cells.

The authors believe that their findings provide proof-of-concept that an implantable antibody-releasing capsule is an effective preventive option for Alzheimer's and other neurodegenerative diseases in which protein build-up plays a role such as Parkinson's disease.

Source: **Brain** ***08 March 2016. DOI: 10.1093/brain/aww036***

FDA approves first coagulation factor-albumin fusion protein to treat patients with hemophilia B

March 4, 2016, The U.S. Food and Drug Administration approved Idelvion, Coagulation Factor IX (Recombinant) Albumin Fusion Protein, to use in children and adults with Hemophilia B. Idelvion is the first coagulation factor-albumin fusion protein product to be approved, and the second Factor IX fusion protein product approved in the U.S. that is modified to last longer in the blood. According to the Centers for Disease Control and Prevention, Hemophilia B is a rare inherited bleeding disorder that prevents blood from clotting normally. The disorder primarily affects males and, rarely, females. People with Hemophilia B can experience repeated episodes of potentially serious bleeding, mainly into the joints, leading to become damaged eventually.

The safety and efficacy of Idelvion were evaluated in two multicenter studies which included a total of 90 adult and pediatric patients with Hemophilia B between 1 and 61 years of age. Idelvion was demonstrated to be effective in controlling bleeding episodes and in managing perioperative bleeding. Idelvion used as prophylaxis led to a significant reduction in the rate of spontaneous bleeding episodes per year despite less frequent infusions of Idelvion. No safety concerns were identified in the studies. The most common side effect observed for Idelvion was headache.

Source: ***U.S. Food and Drug Administration***

FDA expands use of crizotinib, an anti-cancer drug to treat rare form of advanced non-small cell lung cancer

March 11, 2016: The U.S. Food and Drug Administration approved Xalkori to treat people with advanced (metastatic) non-small cell lung cancer (NSCLC) whose tumors have an ROS-1 gene alteration. Xalkori is an oral medication that blocks the activity of the ROS-1 protein in tumors that have ROS-1 gene alterations. This effect on ROS-1 may prevent NSCLC from growing and spreading. The safety and efficacy of Xalkori for the treatment of patients with ROS-1 positive tumors were evaluated in a multi-center, single-arm study of 50 patients with ROS-1 positive metastatic NSCLC. Patients received Xalkori twice daily to measure the drug's effect on their lung cancer tumors. The study was designed to measure overall response rate, the percentage of patients who experienced complete or partial shrinkage of their tumors. Results showed 66 percent of participants experienced a complete or partial shrinkage of their NSCLC tumors, an effect that lasted a median of 18.3 months. The safety results of this study were generally consistent with the safety profile of Xalkori evaluated in 1,669 patients with ALK-positive metastatic NSCLC. The most common side effects of Xalkori are vision disorders, nausea, diarrhea, vomiting, and constipation.

Source: ***U.S. Food and Drug Administration***

Valproate and of risk of abnormal pregnancy outcomes: new communication materials

Children exposed to valproate in utero are at high risk of developmental disorders and congenital malformations. Use the new communication materials below to discuss these risks with patients.

Summary of risks and precautions

- Children exposed in utero to valproate are at a high risk of serious developmental disorders (in up to 30-40% of cases) and congenital malformations (in approximately 10% of cases) .Valproate should not be prescribed to female children, female adolescents, women of childbearing potential or pregnant women unless other treatments are ineffective or not tolerated.
- Valproate treatment must be started and supervised by a doctor experienced in managing epilepsy or bipolar disorder. Carefully balance the benefits of valproate treatment against the risks when prescribing valproate for the first time, at routine treatment reviews, when a female child reaches puberty and when a woman plans a pregnancy or becomes pregnant.
- You must ensure that all female patients are informed of and understand:

  the risks associated with valproate during pregnancy; the need to use effective contraception; the need for regular review of treatment; the need to rapidly consult if she is planning a pregnancy or becomes pregnant

For pharmacists

- Whenever you dispense a medicine related to valproate for a woman of childbearing potential or girl, give her a patient card, unless she confirms that she already has one.
- Encourage her to read the card (example in figures below) and enter her name and date to reinforce her own accountability to consider the information it contains.
- If you manage dispensing services in your organization, ensure that processes are in place to allow these requirements to be met.
- Please continue to report any suspected side effects to valproate or any other medicine on a Yellow Card

For general practitioners

- Valproate treatment must be started and supervised by a specialist experienced in managing epilepsy or bipolar disorder.
- Consider the need to arrange treatment reviews with the relevant specialist for women of childbearing potential and girls who are currently taking valproate.
- If a woman who is taking valproate tells you she is pregnant or would like to have a baby, refer her to the specialist responsible for her care.
- Please continue to report any suspected side effects to valproate or any other medicine on a Yellow Card

Off-label use: risks and advice still apply

- Valproate is not licensed for treatment of conditions other than epilepsy or bipolar disorder in the UK. However, we are aware that these medicines are sometimes used ‘off-label’ (e.g. for migraine or chronic pain). If you are considering initiating or continuing such treatment, the same risks and advice in this article apply.

Source: Drug Safety Update volume 9 issue 6 February 2016: 1.

Many Chronic Pain Sufferers May Overuse Nonprescription Painkillers

According to a recent research painkillers run risk of stomach bleeds, ulcers, and liver damage from meds. Many people with chronic pain ignore dosing instructions on over-the-counter pain medicines and put themselves at risk for an overdose, a new survey suggests.

An overdose of these medicines can result in serious side effects, such as stomach bleeding, ulcers, liver damage and even death, according to the American Gastroenterological Association (AGA).

The AGA-commissioned poll of more than 1,000 U.S. adults aged 30 and older and 251 gastroenterologists found that 43 percent of chronic pain sufferers said they knowingly have taken more than the recommended dose of an over-the-counter (OTC) pain medicine at some point. Common types of OTC pain medicines include acetaminophen (Tylenol) and nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen (Advil, Motrin), naproxen (Aleve) and aspirin.

"Pain is incredibly personal, but taking more than the recommended dose of OTC pain medicine can cause significant stomach and intestinal damage, among other complications," Dr. Byron Cryer, councillor-at-large at the AGA Institute, said in an association news release. Cryer is also an associate dean at the University of Texas Southwestern Medical Center at Dallas.

The survey also found that 38 percent of respondents did not know that combining two or more NSAID pain relievers, or two or more acetaminophen pain relievers, increases the risk of serious health complications.

Many of the gastroenterologists in the poll said many of their chronic pain patients use OTC pain relievers at a higher dose and for longer than recommended. Those patients often don't make the connection between the pain medicines and overdose symptoms, the doctors added.

While 66 percent of those with chronic pain had been plagued by pain for two years or more, only 12 percent had been diagnosed with chronic pain, the survey also found.

People with chronic pain should never try to self-manage their pain with over-the-counter medicines, according to the news release.

If you have chronic pain, talk to your doctor about all the medicines you're taking, read and follow all medicine labels,

Source : American Gastroenterological Association, news release, Jan. 25, 2016

الهيئة العامة للغذاء والدواء "تحذر من تشغيلات لمستحضر أومافن"

1437/05/23

حذرت الهيئة العامة للغذاء والدواء، المستهلكين من استخدام التشغيلات التالية: (0513011-0514005-0515006) لمستحضر أومافن (OMAFEN 400 mg Tablet) 400 ملغم أقراص التابع للشركة الوطنية للصناعات الدوائية بسلطنة عمان، وذلك لعدم مطابقة تلك التشغيلات للمواصفات الفيزيائية بسبب وجود رقائق صغيرة من الألمنيوم في شريط المستحضر. وأوضحت الهيئة في بيان، أنه ثبت لها بعد إجراءات التحقق دخول التشغيلتين التاليتين للسوق السعودي (0513011، 0514005)، وبناء على ذلك ألزمت الهيئة وكيل المستحضر بوقف توزيع هذه التشغيلات وسحب المسوق منها من جميع منافذ البيع. وأوصت الهيئة المستهلكين بتجنب استخدام هذه التشغيلات، مشيرة إلى توفر بدائل عديدة لهذا المستحضر. وأهابت بالمستهلكين إبلاغ المركز الوطني للتيقظ والسلامة الدوائية عند حدوث أي أعراض جانبية للأدوية وذلك على الهاتف: 0112038222 تحويلة: 2340، 2354، 5721، 2356، أو الفاكس 011-2057662، أو البريد الاكتروني : NPC.Drug@sfda.gov.sa .

الغذاء والدواء " تحذر المستشفيات والمستوصفات والممارسين الصحيين من خيوط جراحية مقلدة"

1437/05/12

حذرت الهيئة العامة للغذاء والدواء جميع المستشفيات والمستوصفات وممارسي الرعاية الصحية من خيوط جراحية مقلدة تسوق على أنها منتجات أصلية .وأوضحت الهيئة أن مفتشيها ضبطوا خيوطاً جراحية تحمل اسم "سيمي" في السوق المحلي، بناءً على شكوى من الوكيل، وبعد فحصها والتواصل مع المصنع تبين أنها مقلدة، لذلك لا يمكن ضمان جودة وسلامة المنتج. وطلبت من جميع المستشفيات وممارسي الرعاية الصحية، التأكد من الشراء مباشرة من الشركة الصانعة أو وكيلها أو موزعها المعتمد، واستبدال الجهاز المقلد بجهاز أصلي، وإكمال نموذج الضمان (إذا وجد) ليتمكن الصانع من الاتصال على المشتري (في حال الحاجة إلى اتخاذ إجراءات تصحيحية للسلامة بالموقع أو سحب الأجهزة من السوق). وشددت الهيئة على أهمية إبلاغها في حال الاشتباه بأي منتج مقلد، وذلك عن طريق موقع المركز الوطني لبلاغات الأجهزة والمنتجات الطبية http://ncmdr.sfda.gov.sa ، مع عدم شراء الأجهزة و المنتجات الطبية عن طريق الانترنت .

الغذاء والدواء" تنشر قائمة بـ26 مستحضراً مخالفاً يباع في محال عطارة بطريقة غير نظامية"

1437/04/27

تنشر الهيئة والدواء الهيئة العامة للغذاء والدواء قائمة بـ26 مستحضراً مخالفاً يباع في محلات عطارة بطريقة غير نظامية. وأشارت الهيئة إلى أن بعض تلك المستحضرات مجهولة المصدر والتركيب، في حين أن مستحضرات أخرى لا يسمح بيعها إلا في الصيدليات، ولا تصرف إلا بموجب وصفة طبية، ولها آثار جانبية خطيرة في حال عدم استعمالها بشكل صحيح . وتحمل بعض المستحضرات المخالفة ادعاءات طبية بتسكين وعلاج الألم، بدءاً من آلام الرقبة والعضلات، مروراً بالمفاصل وأمراض البرد والتهاب الأعصاب، وصولاً إلى علاج جميع الآلام . وتدّعي مستحضرات قدرتها على علاج الصداع المزمن، والصرع، والجلطات، والشقيقة، والغيبوبة، والجروح والدمامل والقروح، وحب الشباب، وغيرها . في حين أن مستحضرات أخرى تحمل وعوداً وهمية للمستهلك بتبييض وتفتيح البشرة، وتخفيض الوزن أو زيادته، كما أن بعض المستحضرات ملوثة بكميات عالية من الزئبق السام التي تؤثر بشكل خطير على صحة الإنسان، إضافة إلى تلوث بعض المنتجات بكميات عالية من البكتيريا تفوق المسموح به في المواصفات القياسية السعودية . وأوضحت الهيئة أن بعض المستحضرات تحتوي على مواد تسبب تشوه الجنين . وتتنوع تلك المستحضرات التي تحاول الجهات التي صنعتها إغراء المستهلك باقتنائها، إذ تجد منها كريمات أو كحل أو لصقات أو شراب أو صابون أو بودرة أو دهن أو زيوت أو أعشاب أو عسل أو شامبو .

المصدر: *الهيئة العامة للغذاء والدواء*

استعمال باراسيتامول عند الحوامِل والرُّضع يرتبِطُ بالرَّبو عند الأطفال

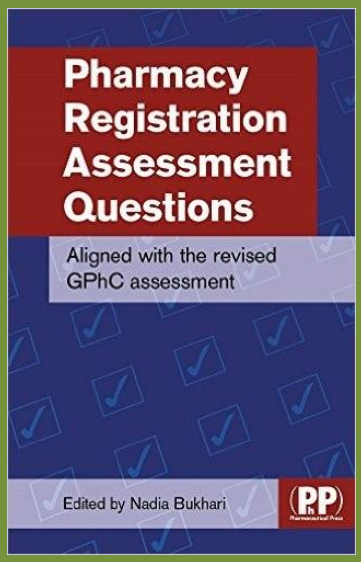
11-Feb-2016

قالَ باحِثون إنَّ الصِّغارَ، الذين يُقدَّم لهم باراسيتامول(Paracetamol) هُم أكثر عرضةً بنسبة الثلث تقريباً للإصابةِ بالرَّبو، حيث وجدوا صِلةً بينَ استِخدام الأمّ لمُسكِّن الألم هذا في فترة الحمل وخطر الرَّبو عند الطفل. ينصحُ الأطباءُ النِّساءَ الحوامِلَ بتجنُّب تناوُل الأدوية قدر الإمكان، ولكن يُعدُّ بارسيتامُول أفضلَ خيارٍ عندما تحتاج الحامِل إلى مُسكِّنٍ للألم للتقليلِ من الحمَّى، وذلك لعدم توفُّر أدلَّةٍ كافيةٍ على أنَّه يُسبِّبُ الضَّرر للصغير. كما يُنصَح أيضاً بتناوُل باراسيتامُول إن احتاج الصِّغارُ إلى مُسكِّناتٍ للألم أو أدويةٍ خافِضةٍ للحرارة . ولكن، وجدت الدِّراسةُ صِلةً مُحتَملةً بين باراسيتامُول والرَّبو عند الأطفال ومع ذلك يرى الباحِثون أنَّ الأمرَ يحتاجُ إلى المزيد من التحرّي، وقالوا إنَّ الصِّلةَ التي وجدوها كانت في حالات استِعمال باراسيتامول عند الحوامِل والصِّغار معاً (في عُمرٍ أقلّ من 6 أشهر)، وأضافوا أنَّ تعرُّض الصِّغار إلى باراسيتامُول زادَ من خطر الرَّبو بنسبة 29 في المائة، كما زاد تعرُّض الحوامل إلى بارستامول من خطر الرَّبو بنسبة 13 في المائة . يجب التنويهُ إلى أنَّ هذه النتيجةَ تحتاج إلى المزيد من الأبحاث التي تشتمِلُ على شرائح بشريَّة أكبر، وذلك قبلَ تغيير النصائح حول استِخدام باراسيتامُول في الحمل وعند الرُّضع .

المصدر: *موسوعة الملك عبد الله بن عبد العزيز العربية للمحتوى الصحي .*

Scientific Books: New Release

Pharmacy Registration Assessment Questions (Tomorrows Pharmacist) by Nadia Bukhari (Author, Editor)



Questions for pharmacy pre-registration trainees to practice for the GPhC registration assessment

This book contains MCQs with descriptive answers for the pre-registration exam. All UK pharmacy trainees must take the registration exam at the end of the pre-registration year in order to practice pharmacy in Great Britain. Written by a former question writer for the Society Registration exam, "Registration Exam Questions" aims to help trainees with their revision by providing a comprehensive list of open- and closed-book questions on topics that are likely to be covered in the exam.

If you want to receive the DPIC bulletin in your E-mail please contact us via: *malarifi@ksu.edu.sa*

Upcoming Conferences

- 11th - 12th April 2016 , 12th Annual Asthma and COPD Conference and Exhibition , at the Holiday Inn Kensington Forum in London, United Kingdom
- April 28-29, 2016 , 5th Global Pharmacovigilance Summit Dubai, UAE
- May 02-04, 2016 , 2nd International Conference and Exhibition on Pharmacology and Ethno pharmacology Chicago, Illinois, USA
- June 20-22, 2016, 4th African Pharma Congress, Cape Town, South Africa
- June 27-29 , 2016 , 5th European Biosimilars Congress , Valencia, Spain
- June 30-July 02, 2016 , 9th World Drug Delivery Summit , New Orleans, Louisiana, USA

Editorial Board

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