

Drug & Poison Information Center BULLETIN



College of Pharmacy

Drug and Poison Information Center

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Repeated Morphine Prolongs Postoperative Pain

Opioids are routinely used to manage pain. In a study rats were treated with morphine for 7 days, beginning immediately laparotomy, while the morphine was tapered in a second group. We found that morphine treatment after laparotomy extended postoperative pain by more than 3 weeks (time × treatment: P < .001; time: P < .001; treatment: P < .05). Extension of postoperative pain was not related to morphine withdrawal, as it was not prevented by dose tapering (time \times treatment: P = .8; time: P <.001; treatment: P = .9). These studies indicate the morphine can have a deleterious effect on postoperative pain

source

https://journals.lww.com/anesthesia.

In this issue

Medical News 1
Pharmaceutical
Authorities News4
Medication Safety
Updates 5
7 الصفحة العربية
Scientific Books: New
Release 8

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Medical News

Depression may raise risk of abnormal heart rate – a study form American Heart Association's (AHA)

A person's risk of developing the common heart disorder atrial fibrillation, or irregular heartbeat, may be increased if they also have depression, according to new data. The AHA's 2018 Heart and Stroke Statistical Update claims that 2.7 million people in the United States have atrial fibrillation. A-fib occurs when the upper chambers of the heart spasm, which therefore prevents them from moving blood into the heart's lower chambers. When blood collects in the heart's upper chamber it can clot, which may lead to stroke. Figures from the National Institutes of Health (NIH) show that, across the U.S., more than 16 million adults experience depression. And, according to the Centers for Disease Control and Prevention (CDC), during any 2-week period, 7.6 percent of people over the age of 12 have depression.

The causes of depression are not well understood, but scientists believe that psychosocial, environmental, behavioral, and genetic factors all play a role.

Depression makes atrial fibrillation '30 percent' likelier In

the recent study, researchers from the Keck School of Medicine at the University of Southern California in Los Angeles analyzed data from the Multi-Ethnic Study of Atherosclerosis (MESA) project.



Medical News (cont..)

More than 6,600 U.S. citizens from a variety of ethnic groups took part in the MESA, and they were followed for 13 years. The participants were aged 62, on average, and they were free from heart disease at the start of the study. Those who took antidepressants and who had the highest scores on a clinical screening test for depression were found to be at more than 30 percent increased risk for A-fib, compared with participants with low scores for depression and who did not take antidepressants. The study was unable to pinpoint exactly how heart function may be disrupted by depression. But, the researchers hypothesize that inflammation and increased levels of some hormones could prevent the heart from being able to maintain a regular rhythm.

Study findings, identify a large portion of Americans who may be at an increased risk for developing atrial fibrillation and who may benefit from more targeted efforts to prevent this arrhythmia. If study findings are affirmed in future studies, especially those that formally assess for clinical depression, then we will need to see if treating depression may, in fact, lower the risk for atrial fibrillation

Nonsteroidal anti-inflammatory drug could stop Alzheimer's disease – a population based study

Nonsteroidal anti-inflammatory drugs such as ibuprofen today, taking patients to ease a headache or alleviate back pain. But there might be more to this common medication than pain relief; a new paper suggests that a daily dose of ibuprofen could prevent Alzheimer's disease. Recently published study in the Journal of Alzheimer's Disease describes how ibuprofen could reduce inflammation caused by an Alzheimer's-related peptide.

Alzheimer's disease is the most common form of dementia. It is estimated that around 5.7 million adults in the United States are living with the disease. This number is predicted to rise to almost 14 million by 2050. The signs and symptoms of Alzheimer's for most people with Alzheimer's—those who have the late-onset variety—symptoms first appear in their mid-60s. Signs of early-onset Alzheimer's begin between a person's 30s and mid-60s. Memory problems are typically one of the first signs of cognitive impairment related to Alzheimer's disease. Decline in non-memory aspects of cognition, such as word-finding, vision/spatial issues, and impaired reasoning or judgment, may also signal the very early stages of Alzheimer's disease. Alzheimer's disease progresses in several stages: preclinical, mild (sometimes called early-stage), moderate, and severe (sometimes called late-stage).

The search continues for the exact causes of Alzheimer's, but a sticky protein called beta-amyloidis believed to play a role in the disease. Beta-amyloid can clump together and form plaques in the brain. These plaques will interfere with brain cell communication, which can lead to memory loss, behavioral changes, and many other symptoms characteristic of Alzheimer's disease

Medical News (cont..)

In a study published last year results revealed that a beta-amyloid peptide, known as amyloid-beta 42 (Abeta 42) — is present in saliva, as well as the brain, and that levels of this peptide are higher in adults who are at greater risk of Alzheimer's. Based on those results, suggests that a saliva test could be used to predict the risk of Alzheimer's disease years before symptoms arise. People who are at risk of developing Alzheimer's exhibit the same elevated Abeta 42 levels as people who already have it; moreover, they exhibit those elevated levels throughout their lifetime so, theoretically, they could get tested anytime.

In present study researchers claim that ibuprofen — a widely used nonsteroidal anti-inflammatory drug (NSAID) could prevent the development of Alzheimer's in people with high levels of Abeta 42. According to previous research suggested that Abeta 42 triggers an inflammatory response. This response could be reduced by ibuprofen and other NSAIDs, which could stop Alzheimer's in its tracks.

The research suggested that identifying the risk of Alzheimer's through a saliva test would offer people the opportunity to prevent Alzheimer's development through a daily dose of ibuprofen. Knowing that the prevalence of clinical Alzheimer's disease commences at age 65, it is recommend that people get tested 10 years before, at age 55, when the onset of Alzheimer's would typically begin. If they exhibit elevated Abeta 42 levels then, that is the time to begin taking daily ibuprofen to ward off the disease. It's revealed that the saliva test as a true breakthrough because it points in a direction where [Alzheimer's disease] can eventually be eliminated

The Alzheimer's Society in the United Kingdom, believes that it is far too soon to be recommending daily ibuprofen for Alzheimer's prevention. According to Population based studies which gather large amounts of information from medical records from thousands of people, have thrown up an idea that taking ibuprofen and other over-the-counter anti-inflammatories might be linked to a lower risk of dementia



Daily ibuprofen recommendation 'premature But results of clinical trials with these drugs have been disappointing so far. The researchers suggestion in this paper that taking a daily anti-inflammatory drug as soon as a positive result for dementia risk is shown by a saliva test is premature, The author of the study also notes the risks of long-term NSAID use, including intestinal bleeding and stomach ulcers. NSAIDs may also interact with other medications, such as warfarin, and produce harmful effects. It is always recommend talking to your doctor before changing your medication.

Source; Medical news today; https://www.medicalnewstoday.com/articles/321352.php

Pharmaceutical Authorities News

Increased risk of death revealed with two blood pressure drugs

High blood pressure, or hypertension, is a major risk factor for heart disease, the leading cause of death in the United States. But a new study has found that two classes of medication that are commonly used to lower blood pressure could present a death risk all on their own. Now, a person is considered to have hypertension if their systolic blood pressure (the top number) is 130 millimeters of mercury (mmHg) or higher, and their diastolic blood pressure (the bottom number) is 80 mmHg or higher. Previous research, however, has discovered that consistency is key for blood pressure levels. A study published in *The BMJ* in 2016, for example, associated higher variability of systolic blood pressure with a 15 percent increase in all-cause mortality.

Two medications 'should be avoided'

For the present study, the researchers analyzed the data of over 10,500 adults with high blood pressure. The participants had their blood pressure measured at least seven times between January 2007 and December 2011, and the type of blood pressure medication they were using was monitored.



Researchers assess whether certain classes of blood pressure medication were associated with variability in blood pressure levels. The study revealed two classes of blood pressure medication that were linked to higher blood pressure variability in subjects: alpha blockers and alpha-2 agonists. Alpha blockers — which include doxazosin mesylate and prazosin hydrochloride — work by dilating the blood vessels. Alpha-2 agonists, such as methyldopa, work by targeting sympathetic nervous system activity, thereby reducing blood vessel constriction. Based on the study results, it is advisable that two medications should not be used to treat hypertension.

Patients should know what their blood pressure is, and if it's up and down all the time, the patient should work with their physician to explore options for the best blood pressure medications that will reduce variances. Where possible, the two types of medications that show an increase in variances should be avoided. According to research it is suggested that ACE inhibitors, angiotensin receptor blockers, calcium channel blockers, and thiazide diuretics may be safer treatment options for people with hypertension. "People who are on other types of blood pressure medications have an increased risk of death.

Source; https://www.medicalnewstoday.com/articles/321194.php

Medication Safety Updates

Pressurised metered dose inhalers (pMDI): risk of airway obstruction from aspiration of loose objects

Pressurized metered dose inhalers (pMDI) are widely used for delivery of rescue and maintenance bronchodilator and anti-inflammatory therapies for asthma. The mouthpiece of the inhaler is protected by a removable plastic cover. To avoid accidental inhalation of the mouthpiece cover, the patient must fully remove the cover before inhaling a dose. If the inhaler is stored without the cover, loose objects can become trapped within the mouthpiece and inhaled into the back of the throat, resulting in coughing. In some cases, objects were aspirated, causing airway obstruction.

Advice for healthcare professionals:

Train patients in the correct use of their inhaler; instructions for patients are provided in the patient information leaflet. Tell patients to remove the mouthpiece cover fully, shake the inhaler to remove loose objects that may not be visible, and check the inside and outside of the mouthpiece are clear before inhaling a dose, to prevent objects entering the mouthpiece during storage, remind patients to replace the cover immediately after use, ensuring it clicks into place

Pharmacists dispensing a pMDI should emphasize to patients the need to clean the device regularly by following the instructions in the patient leaflet and to inspect the device for signs of damage; devices that are damaged should be replaced immediately. Please continue to report adverse incidents during use of inhalers, as well as suspected adverse reactions to the medicine, on a

https://www.gov.uk/drug-safety-update

Parenteral amphotericin B: reminder of risk of potentially fatal adverse reaction if formulations confused

(Parenteral amphotericin B is available as lipid-based (AmBisome, Abelcet) and non-lipid-based (Fungizone) formulations for the treatment of severe fungal infections. These different formulations of amphotericin B have different dose requirements. The appropriate dose and method of administration differ markedly between the marketed parenteral formulations of amphotericin B and they are therefore not interchangeable. Amphotericin B overdoses may result in fatal cardiac or cardiorespiratory arrest.

Advice for healthcare professionals:

When prescribing, communicating and dispensing amphotericin products, use both the complete generic name and the proprietary name: non-lipid amphotericin (Fungizone), liposomal amphotericin (AmBisome), lipid-complex amphotericin (Abelcet)

verify the product name and dose before administration, especially if the dose prescribed exceeds 1.5 mg/kg—the maximum recommended dose for Fungizone.potentially fatal cardiac or cardiorespiratory arrest. The total daily dose of Fungizone should not exceed 1.5 mg/kg.

Source https://www.fda.gov/Drugs/DrugSafety.

Medication Safety Updates

FDA Approves Jynarque (tolvaptan) to Slow Kidney Function Decline in Rapidly Progressing Autosomal Dominant Polycystic Kidney Disease

April 24, 2018 the U.S. Food and Drug Administration (FDA) has approved Jynarque as the first drug treatment to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). The efficacy of tolvaptan was demonstrated in two pivotal trials, lasting one year and three years, respectively. In the one-year REPRISE study, the primary endpoint was the treatment difference in the change of eGFR from pretreatment baseline to post-treatment follow-up, annualized by dividing by each subject's treatment duration. In the randomized period, the change of eGFR from pretreatment baseline to post-treatment follow-up was –2.3 mL/min/1.73 m2/year with tolvaptan as compared with –3.6 mL/min/1.73 m2/year with placebo, corresponding to a treatment effect of 1.3 mL/min/1.73 m2/year (p <0.0001). In the three-year TEMPO 3:4 study, tolvaptan reduced the rate of decline in eGFR by 1.0 mL /min /1.73m2 /year (95 % confidence interval of 0.6 to 1.4) as compared to placebo in patients with earlier stages of ADPKD. In the extension trial, eGFR differences produced by the third year of the TEMPO 3:4 trial were maintained over the next 2 years of Jynarque treatment.

Source https://www.drugs.com

FDA Approves Olumiant (baricitinib) 2 mg Tablets for the Treatment of Adults with Moderately-to-Severely Active Rheumatoid Arthritis

June 1, 2018 The U.S. Food and Drug Administration (FDA) has approved the 2-mg dose of Olumiant (baricitinib), a once-daily oral medication for the treatment of adults with moderately-to-severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) inhibitor therapies. The Olumiant clinical trial program included the, double-blind, placebo-controlled study in which 527 patients were randomly assigned to receive Olumiant 2 mg, baricitinib 4 mg or placebo, results showed that significantly higher ACR20 response rates and improvement in all individual ACR20 component scores were observed at Week 12 with Olumiant. The study found that patients treated with Olumiant had significantly higher rates of ACR20 response versus placebo-treated patients at Week 12 (49% of Olumiant-treated patients versus 27% of placebo-treated patients). Olumiant also demonstrated early symptom relief, with ACR20 responses seen as early as Week 1. Patients treated with Olumiant reported significant improvements in physical function based on the Health Assessment Questionnaire Disability Index (HAQ-DI) compared to placebo-treated patients. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with Olumiant, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

Source; https://www.drugs.com

الصفحة العربية

"الغذاء والدواء" تعلق تسجيل (Metaphage 500 mg) لعدم تكافئه حيوياً مع المستحضر المرجعي

18/08/1439

علّقت الهيئة العامة للغذاء والدواء تسجيل مستحضر Metaphage 500 mg لعدم تكافؤ المستحضر حيوياً مع المستحضر المرجعي. وخاطبت الهيئة الجهات الصحية لسحب المستحضر في حال وجوده لديها، كما خاطبت وكيل المستحضر لسحبه من جميع الجهات المستفيدة، ودعت مستخدمي الدواء لمراجعة أطبائهم.

ويحمل المستحضر الذي تصنعه "الشركة الكويتية السعودية" الاسم التجاري Metaphage 500 mg والاسم العلمي Metaphage 500 mg ورقم التسجيل 44-352-04 .

وجاء تعميم الهيئة بناءً على قرار لجنة تسجيل شركات ومصانع الأدوية ومنتجاتها بالهيئة رقم sfda/39/947/42 القاضي بتعليق تسجيل المستحضر .

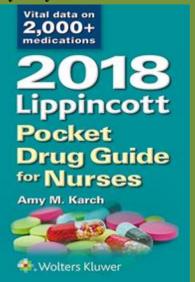


المصدر: الهيئة العامة للغذاء والدواء .

Scientific Books: New Release

2018 Lippincott Pocket Drug Guide for Nurses Sixth Edition by Amy M. Karch MSN RN

The 2018 Lippincott Pocket Drug Guide for Nurses provides current, vital drug information "in a nutshell." Based on the popular Lippincott Nursing Drug Guide, this handy pocket guide by the same author gives essential information on over 2,000 medications in an easy-access A-to-Z format. The "mini" drug monographs include generic and trade names, drug class, pregnancy risk category and controlled substance schedule, "black box" warnings, indications & dosages, dose adjustments, adverse effects, drug interactions, nursing considerations, and patient teaching. A special section reviews Patient Safety and Medication Administration. Appendices cover topical and ophthalmic medications, laxatives, combination products, contraceptives, biological agents (vaccines), and more.



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Upcoming Conferences

- September 10-11, 2018 Zurich, Switzerland. 6th International Conference on Advanced Clinical Research and Clinical Trials. Theme: Encouraging World towards conducting Clinical Research and Clinical Trials
- ❖ September 24-25, 2018 Abu Dhabi, UAE Theme: Global Innovations & Recent Advancements in Pharmaceutical Sciences
- ❖ September 17-18, 2018 | Philadelphia, Pennsylvania, USA. 15th International Conference on Pharmaceutical Formulations & Drug Delivery Theme: Looming technologies in Pharmaceutical Formulations and Drug Delivery.

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