

Drug & Poison Information Center BULLETIN



College of Pharmacy

Drug and Poison Information Center

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Elevated blood sugar in heart failure patients linked with early death

New research suggests that people who arrive the hospital emergency department with acute heart failure should have blood sugar levels tested on arrival to identify those at a high risk of early death, further hospitalizations or the development of health issues. such diabetes.

written

bv Hannah

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Medical News

Death rates from cancer continue to drop – a report from the American Cancer Society

The latest annual report from the American Cancer Society shows that death rates from cancer in the US are continuing to fall, "giving reasons to celebrate but not to stop," according to the voluntary health organization whose goal is the eradication of cancer.

In figures to be published in *CA: A Cancer Journal for Clinicians*, the American Cancer Society (ACS) show how the death rate from cancer in the US has dropped by 22% since its peak in 1991. They say this means about 1.5 million deaths from cancer have been avoided in the last 20 years.

The ACS estimates that in 2015, the US will see a total of 1,658,370 new cancer cases and 589,430 deaths due to the disease. Cancer was responsible for nearly 1 in 4 deaths in the US in 2011, making it the second leading cause of death overall close behind heart disease. The new figures show that between 2007 and 2011, new cancer cases in men fell by 1.8% a year. In women, it stayed much the same. Death rates over the same period fell by 1.8% per year in men and 1.4% per year in women. The ACS argues that pushing the fight against cancer across all segments of the population could lead to even more progress.

Cancer deaths reflect nationwide differences in health and other factors

The extent to which death rates in the US have fallen varies by state, with a general pattern showing less of a decrease in the south than the north-east - reflecting state-by-state differences in health factors. For example, rates of smoking and obesity - two big modifiable risk factors for cancer - follow a similar south versus north-east pattern. The gap between rich and poor, and disparities in health care access - both of which are increasing - also have an effect, notes the report.

Rates of lung, colon, prostate and breast cancers - which account for nearly half of all cancer deaths among men and women - have all shown large drops. However, lung cancer still stands out as the cancer that kills the most people in the US - accounting for more than 1 in 4 (27%) cancer deaths.

Medical News (cont..)

Earlier detection, treatment, reduced tobacco use may explain fewer cancer deaths

As tobacco use has declined in the US, so have rates of death to lung cancer. Between 1990 and 2011, they fell 36% among men, and between 2002 and 2011, they fell 11% among women. American women did not take up smoking in large numbers until about 20 years after men, and their use of tobacco did not start to fall until the late 1990s, whereas in men, the rates began to drop in the mid-1980s. The difference in drop in deaths to lung cancer between the two groups follows a similar pattern.

Over the last 20 years, breast cancer deaths have fallen by over a third (35%), while deaths from prostate and colon cancers are each nearly half (47%) the levels they were 2 decades ago. The ACS say these huge reductions are mainly due to earlier detection and treatment. The three most common cancers expected to occur in American men in 2015 are prostate, lung and colon cancer - accounting for about half of new cases. In women, the three most common cancers are expected to be breast, lung and colon cancer - also to account for around half of all new cases of cancer. **Prostate cancer** will account for around 25% of new diagnoses in men in 2015, while in women, **breast cancer** will account for around 29% of new cases, the report predicts.

Dr. John R. Seffrin, CEO of ACS, comments:

"[Cancer] is already the leading cause of death among adults aged 40 to 79 and is expected to overtake heart disease as the leading cause of death among all Americans within the next several years.

"The change may be inevitable, but we can still lessen cancer's deadly impact by making sure as many Americans as possible have access to the best tools to prevent, detect, and treat cancer."

Medical News Today recently reported key highlights of the 25th anniversary edition of **America's Health Rankings**, where reduction in smoking tops the list of top 10 successes. Since 1990, smoking has fallen by 36% in the US, from 29.5% to 19.0% of adults who regularly smoke.

In contrast, however, obesity has increased by 153% in the same period, from 11.6% to 29.4% of adults, while physical inactivity - at 23.5% of adults - has not changed much in the last 10 years.

Written by Catharine Paddock PhD

Drug for Bladder Problems May Help Control Weight, Too

A drug already used to treat overactive bladder may also someday help control weight by boosting the metabolic powers of brown fat, a small study suggests.

While white fat stores energy, brown fat burns energy to generate body heat. In the process, it can help maintain body weight and prevent obesity, at least in animals, previous studies have shown. In the new study, researchers gave 12 healthy, lean young men a high dose of the drug mirabegron (Myrbetriq), and found that it boosted their metabolic rate. The drug "activates the brown fat cells to burn calories and generate heat," said study researcher Dr. Aaron Cypess. He is section head of translational physiology at the U.S. National Institute of Diabetes and Digestive and Kidney Diseases.

Medical News (cont..)

When the activity of the drug peaked, "the metabolic rate went up by 13 percent on average," Cypess said. That translates to about 203 calories, he said. However, Cypess said that doesn't necessarily mean the men would burn an extra 203 calories a day over the long-term. The researchers don't yet know how long the calorie-burning effect might last, as they didn't follow the men over time.

The researchers projected the three-year weight loss would be about 22 pounds. The study was published Jan. 6 in *Cell Metabolism*. Cypess conducted the research while working at the Joslin Diabetes Center and Harvard Medical School. The study was funded by the U.S. National Institutes of Health, with no drug company involvement.

The men, whose average age was 22, took a single dose of the drug in one session and took a single dose of a placebo in another, serving as their own comparisons. The researchers measured metabolic rate by scans, including positron emission tomography (PET) and CT scans. The effects of the drug on fat-burning, Cypess said, would be "mild to moderate if sustained."

The drug works by activating what is known as a beta 3-adrenergic receptor, found on the surface of brown fat cells. It is also found on the urinary bladder cells, and the drug works to calm an overactive bladder by relaxing muscle cells there, he said. Much more research is needed, Cypess said. The study was small, including young men who on average had healthy body weights. Much less is known about the role of brown fat in people than in animals, he said. In future research, he said he hopes to study larger groups, including women.

The dose given to the men was 200 milligrams (mg) a day, versus 50 mg for overactive bladder. Cypess cautioned that people should not take the drug expecting to lose weight. While the 200-mg dose was generally well-tolerated, it did raise the heart rate to abnormally high levels, increasing it by 14 beats a minute on average, which Cypess said was too high. He hopes to investigate lower doses in the future to see if they are also effective, he said.

Connie Diekman, director of university nutrition at Washington University in St. Louis, reviewed the findings. "I would put this study into the category of interesting research that needs much more study before there is any consideration of this drug therapy as an aid to weight loss," she said. The study is small, and "leaves many questions related to real impact on weight loss," she said. "The subjects were all lean, so how this drug might impact an overweight subject is not clear," Diekman added. The amount of projected weight loss is small if an individual is overweight, she said. And, as noted by the researchers, the dose used could lead to an abnormally high heart rate, which is not healthy, she said. Cypess agreed that much more research is crucial. If more research bears out the findings on the drug, "a realistic hope is that it will be incorporated into a general plan of saying, 'Eat responsibly, exercise regularly and keep your brown fat active," he said. Currently, he said, there is no practical way for people to find out how much brown fat they have, "but it is an active area of research."

Pharmaceutical Authorities News

FDA approves weight-management drug Saxenda

(December 23, 2014)

The U.S. Food and Drug Administration approved Saxenda as a treatment option for chronic weight management in addition to a reduced-calorie diet and physical activity. The drug is approved for use in adults with a body mass index (BMI) of 30 or greater (obesity) or adults with a BMI of 27 or greater (overweight) who have at least one weight-related condition such as hypertension, type 2 diabetes, or high cholesterol (dyslipidemia). BMI, which measures body fat based on an individual's weight and height, is used to define the obesity and overweight categories.

The safety and effectiveness of Saxenda were evaluated in three clinical trials that included approximately 4,800 obese and overweight patients with and without significant weight-related conditions. All patients received counseling regarding lifestyle modifications that consisted of a reduced-calorie diet and regular physical activity.

Results from a clinical trial that enrolled patients without diabetes showed that patients had an average weight loss of 4.5 percent from baseline compared to treatment with a placebo (inactive pill) at one year. In this trial, 62 percent of patients treated with Saxenda lost at least 5 percent of their body weight compared with 34 percent of patients treated with placebo. Results from another clinical trial that enrolled patients with type 2 diabetes showed that patients had an average weight loss of 3.7 percent from baseline compared to treatment with placebo at one year. In this trial, 49 percent of patients treated with Saxenda lost at least 5 percent of their body weight compared with 16 percent of patients treated with placebo.

Patients using Saxenda should be evaluated after 16 weeks to determine if the treatment is working. If a patient has not lost at least 4 percent of baseline body weight, Saxenda should be discontinued, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment. Serious side effects reported in patients treated with Saxenda include pancreatitis, gallbladder disease, renal impairment, and suicidal thoughts. Saxenda can also raise heart.

Source: U.S.FDA

FDA approves Opdivo for advanced melanoma

December 22, 2014

The U.S. Food and Drug Administration today granted accelerated approval to Opdivo (nivolumab), a new treatment for patients with unresectable (cannot be removed by surgery) or metastatic (advanced) melanoma who no longer respond to other drugs.

Melanoma is the fifth most common type of cancer in the United States. It forms in the body's melanocyte cells, which develop the skin's pigment. The National Cancer Institute estimates that 76,100 Americans will be diagnosed with melanoma and 9,710 will die from the disease this year. Opdivo works by inhibiting the PD-1 protein on cells, which blocks the body's immune system from attacking melanoma tumors. Opdivo is intended for patients who have been previously treated with ipilimumab and, for melanoma patients whose tumors express a gene mutation called BRAF V600, for use after treatment with ipilimumab and a BRAF inhibitor. Opdivo's efficacy was demonstrated in 120 clinical trial participants with unresectable or metastatic melanoma. Results showed that 32 percent of participants receiving Opdivo had their tumors shrink (objective response rate). This effect lasted for more than six months in approximately one-third of the participants who experienced tumor shrinkage.

Medication Safety Updates

Ebola: new study is first to report vaccine success in Africa

To date, almost 7,000 deaths have been reported as a result of the 2014 Ebola outbreak, with the majority occurring in West Africa. Now, a new study published in *The Lancet* is the first to reveal the success of an Ebola vaccine in an African population, as well as the success of a vaccine for the closely related Marburg virus. Both **Ebola** and Marburg belong to a family of viruses called *Filoviridae*, or filoviruses, which are known to cause severe hemorrhagic **fever** in both humans and nonprimates. There are five species of Ebola virus; the Zaire (EBOV) and Sudan (SUDV) strains are behind the 2014 outbreak. Marburg is a single-strain virus.

In their phase 1 clinical trial, led by Dr. Julie Ledgerwood of the National Institutes of Allergy and Infectious Diseases (NIAID), the team tested the effectiveness of two vaccines - one for the EBOV and SUDV strains of Ebola (EBO vaccine) and one for Marburg (MAR vaccine) - in 108 healthy participants aged 18-50 from Kamapala, Uganda, between November 2009 and April 2010. The vaccines, created by researchers from the NIAID, are made up of protein structures on the outer surface of the viruses. These generate an immune response in the body but do not allow viral replication.

Effectiveness and safety of vaccines 'particularly encouraging'

At study baseline and at 4 and 8 weeks later, participants were randomly assigned to receive an injection of either the EBO vaccine, the MAR vaccine, both vaccines or a placebo. The team found that the EBO and MAR vaccine - when administered separately and together - effectively triggered an immune response in participants by neutralizing antibodies and T cells against the proteins of the viruses.

Among participants who received the EBO vaccine, 17 of 30 displayed an antibody response to the Ebola Zaire protein 4 weeks after the last injection, while 14 of 30 participants who received both the EBO and MAR vaccine showed an antibody response against the protein. The researchers note, however, that these antibodies were at undetectable levels within the following 11 months. Both of the vaccines were well tolerated by participants, the researchers say, with only one adverse reaction - a low white blood cell count reported in one participant who received the MAR vaccine only. This case, however, was not believed to be triggered by the vaccine.

Results have already boosted clinical testing of another Ebola vaccine

Dr. Ledgerwood notes that the results of this study have already "formed the basis" and boosted clinical testing of another Ebola vaccine, known as cAd3-EBO, which is delivered using a chimpanzee "cold" virus. A reported by *Medical News* the vaccine was revealed to have **induced long-term immunity against Ebola in monkeys**, which led the National Institutes of Health to announce the vaccine would be entering phase 1 clinical trials in the US. It is also entering expanded trials in Europe and Africa. In an editorial linked to this latest study, Dr. Saranya Sridhar, of the Jenner Institute at the University of Oxford in the UK, says the findings should be a "focal point" for Ebola vaccine development.

"With the uncharitable benefit of hindsight in view of the evolving 2014 Ebola outbreak, we must ask ourselves whether a filovirus vaccine should have been in more advanced clinical development," she says, adding:

Written by Honor Whiteman

Medication Safety Updates

Stroke falls one place to fifth leading cause of death in US

According to Centers for Disease Control and Prevention report, stroke has dropped one place in the top 10 leading causes of death in the US, becoming the fifth leading cause of death during 2013.

Stroke has swapped positions with unintentional injuries in the list, which killed 1,579 more people than stroke in 2013. However, there were no other changes in position between 2012 and 2013 in the list. Between them, the report says, these 10 causes accounted for 73.6% of all deaths in the US in 2013. In 2012, 36.9% of deaths in the US were caused by stroke, while in 2013, this dropped slightly to 36.2%.

Although the death rate from **heart disease** also dropped slightly over the same period, heart disease remains the leading cause of death in the US, with **cancer** and chronic lower respiratory diseases in second and third place in the list, respectively. Commenting on the Centers for Disease Control and Prevention (CDC) report, the American Heart Association (AHA) hypothesize that the drop in deaths from stroke is due to advances in the treatment and prevention of stroke. In particular, the AHA note, there are more stroke centers now operating across the US, and there has also been an improvement in acute care of stroke.

"However, although mortality from stroke is dropping," says Dr. Ralph Sacco, past president of the AHA and chairman of neurology at the University of Miami Miller School of Medicine, "we know that the number of people having strokes in the US is rising each year due to the aging of our population and other signs that strokes have increased in younger groups." "Still, far too many people are still dying from stroke, and too many people are suffering greatly from this disease," concurs AHA president Dr. Elliott Antman.

However, Dr. Antman says that the fact the death rate is declining is gratifying news, adding, "These statistics are a tribute to the many courageous survivors, health care professionals, researchers, volunteers and everyone else committed to fighting stroke."

Stroke is more disabling than it is fatal

Stroke - which is more disabling than it is fatal - remains a leading cause of disability in the US. The AHA statement reminds that the number of people suffering from painful and debilitating after-effects of stroke remains a major cause of concern. AHA CEO Nancy Brown summarizes:

"There is a great deal to be done on behalf of stroke survivors, who very often face highly debilitating consequences in the aftermath of this severe cardiovascular event. We are committed to standing by their side as we continue striving for new breakthroughs in stroke prevention, treatment and rehabilitation."

One recent advance in stroke research was the identification of a drug target for prevention of **stroke-related brain damage**. *Medical News* reported on a study of almost 34 million people who received **Medicare Fee-For-Service** between 1999 and 2011, which found that hospitalization rates for stroke declined by 33.6% during the study period, while risk of death reduced by 13%.

Written by **David McNamee**

الصفحة العربية

الهيئة العامة للغذاء والدواء " تنبه إلى خلل في حقن قد تمنع وصول الأنسولين للمريض "



08/03/1436

ووجهت "الغذاء والدواء" إرشادات للمرضى في حال انفصال الأنبوب، تشمل عدم محاولة إعادة توصيل الأنبوب واستبدال مجموعة الحقن فوراً، ومعالجة أي ارتفاع في مستوى سكر الدم إضافة إلى إبلاغ الهيئة إذا كان لديهم أي من هذه الأجهزة المتأثرة.

مجموعات الحقن (Infusion Sets)	الشركة (Company)
مینی مید سلوت MiniMed SilhouetteTM	میدترونیك میني مید
مینی مید شور - تی MiniMed Sure-TTM	(Medtronic MiniMed)
1 أكبو تشيك تقدر (Accu-Chek® Tender I)	
أكيو تشيك تندر 2	
(Accu-Chek® Tender II)	روش دیاقنوستکس
أكيو تشيك تندر لينك 1	(Roche Diagnostics)
(Accu-Chek® TenderLink I)	
أكيو تشيك تندر لينك 2	
(Accu-Chek® TenderLink II)	
كومفورت (ComfortTM)	نیماس (Animas).
كومفورت شورت (ComfortTM Short)	
(ContactTM Detach) کونتاکت دیتاتش	
كومفورت (ComfortTM)	هارادا
كومفورت شورت (ComfortTM Short)	(Harada)

الغذاء والدواء" تحذر من "زينو كافيه": مغشوش بمواد دوائية ويحمل ادعاءات مضللة

15/02/1436

حذرت الهيئة العامة للغذاء والدواء المستهلكين من مستحضر زينو كافيه لأنه يحمل ادعاءات مضللة وجرى غشه بمواد دوائية وتروج محال عطارة ومواقع الكترونية أنه يشفي من نوبات الربو ومن حساسية الأنف والصدر والجيوب الأنفية، ومن الالتهابات المزمنة والحادة كالتهاب العظام وآلام المفاصل وأكزيما الجلد والصدفية والروماتيد وقرحة القولون المزمنة.

وأوصت الهيئة المستهلكين بتجنب هذا المستحضر و التخلص من ما لديهم من عينات .



المصدر: الهيئة العامة للغذاء والدواء

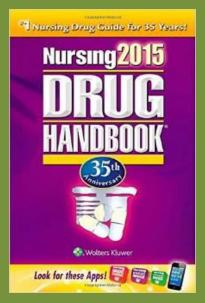
Scientific Books: New Release

Nursing 2015 Drug Handbook, 35th Anniversary Edition (Nursing Drug Handbook)

(Lorraine Hallowell (Editor), Karen C. Comerford (Editor)

The 35th edition of the best-selling, original drug handbook for nurses **provides complete monographs for more than 900 generic and** thousands of brand-name drugs. Monographs are consistently formatted for ease of use and focus on the practical information that nurses need.

Each monograph consists of generic and trade names, pronunciation key, pregnancy risk category, pharmacologic class, controlled substance schedule (if applicable), available forms, indications and dosages, administration (with drug incompatibities for I.V. drugs), action (including tables showing route, onset, peak, duration, and half-life), adverse reactions, interactions, effects on lab test results, contraindications, nursing considerations, and patient teaching.



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Upcoming Conferences

- ❖ 7th 8th January drug carries in medicine and biology in London, India
- ❖ 15 January 2015 the FDA drug approval process Frontiers at online in Mississauga ON, Canada
- ❖ 26th 28st January 2015 4th drug formulation and bioavailability in Boston united states
- ❖ 24nd 26th February 2015 'e -pharma 2015' at Hilton new York Mid town in New York
- ❖ 16^{th-} 17th march 2015 missing data in clinical trials Loews Philadelphia united states

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