

Recent Pharma News

Kids Can Get Migraines Too

February 17, 2015 - Migraines aren't just a problem for adults. About 6% of children and more than one-quarter of teens aged between 15 to 17 have migraines, according to the American Migraine Foundation (AMF). "There are many things that can be done if your child suffers from migraine, or if you suspect that he or she does," foundation chair Dr. David Dodick, a professor of medicine at the Mayo Clinic College of Medicine in Scottsdale, Arizona said in an AMF news release.

If you suspect your child has migraines, take him or her to a doctor to be assessed and receive treatment if necessary. Options include treatment to stop the pain and prevent a migraine from getting worse, along with measures to prevent or reduce the frequency, severity and duration of migraines.

If your child is prescribed a migraine medication, it's important for you to make sure he or she takes the medicine as directed. Inform your doctor if there are changes in your child's migraines, such as becoming more frequent or severe. A new treatment approach may be required, according to the headache experts.

A number of factors may contribute to your child's migraines, such as too little or too much sleep or stress. Parents need to help their children follow healthy lifestyles and cope with stress. Recent research in stress management suggests that a type of counseling called cognitive behavioral therapy can benefit children with chronic headache, according to the AMF. Other potentially helpful stress-control techniques include relaxation therapy and biofeedback.

Keeping a migraine diary can help youngsters understand why they get migraines and how to prevent them. The diary tracks migraines, the severity, how long they last, what patients were doing before and during the migraine, and what foods they ate.

Mobile phone apps may be an ideal way for children and teens to track their migraines and to take their medications as prescribed, the experts suggested.

Alirocumab shows promise as treatment to reduce LDL-cholesterol in Phase III study

February 17, 2015 -- A recently published clinical trial report reviewing the first completed Phase III study in the ODYSSEY development program has shown that alirocumab showed significantly better LDL-C lowering than ezetimibe, with a comparable safety profile to ezetimibe. The report, which is published in the January issue of *Future Cardiology*, provides a comprehensive overview of the ODYSSEY MONO trial, including detail on the study design, data analysis, results and discussion on the implications of the findings, authored by lead investigator of the trial Eli M Roth.

LDL-cholesterol (LDL-C) is considered to be a major modifiable risk factor for the development of atherosclerosis and cardiovascular disease (CVD), the leading cause of death worldwide. LDL-C is identified as the primary target of cholesterol-lowering therapy in both North American and European guidelines. Statins are the recommended first-line therapy for lowering LDL-C.

Alirocumab (formerly SAR236553/REGN727) is a fully human mAb to PCSK9 - the first in this class of drugs to complete a Phase III trial, and reported to have a significant role in the regulation of LDL-C - being developed jointly by Sanofi (France) and Regeneron (NY, USA).

'Mindfulness' May Help Ease Sleep Problems for Seniors

February 16, 2015 -- Mindfulness meditation may help older adults get a better night's sleep, a small study suggests. Researchers found that among 49 older adults with sleep problems, those who learned mindfulness practices started sleeping better within six weeks. In fact, they did better than their counterparts who were given conventional lessons on good sleep habits, the study authors said. Experts said the findings, published online Feb. 16 in the journal *JAMA Internal Medicine*, are encouraging.

Sleep problems are affected by the mind. When people have difficulty sleeping, they often start to worry about it -- and that anxiety can worsen their sleep problems. On top of that, poor sleep itself can lead to psychological "distress," such as depression symptoms. There is a cyclical pattern here between wakefulness, sleep disruption, worry and mood. By learning non-judgmental mindful awareness people can begin to see their thoughts and feelings without reacting to them. In basic terms, it helps them relax -- a "necessary prerequisite" for sleep.

Smoking Linked to Damage in the Brain, Researchers Find

February 13, 2015 -- Smoking may damage part of the brain by causing thinning in a crucial area, new research shows. The study included more than 500 male and female smokers, former smokers and nonsmokers who were an average of 73 years old.

Brain scans revealed that current and former smokers had a thinner cortex than those who never smoked. The cortex is where important thought processes such as memory, language and perception occur.

The researchers also found that stopping smoking leads to partial restoration of the cortex's thickness, but the process is slow and incomplete. Heavy ex-smokers who hadn't smoked for more than 25 years still had a thinner cortex than nonsmokers, the researchers found. The cortex grows thinner with age, but smoking appears to speed that thinning. And, a thinner cortex is associated with mental decline, the researchers noted. The study was published online Feb. 10 in the journal *Molecular Psychiatry*.

"Smokers should be informed that cigarettes could hasten the thinning of the brain's cortex, which could lead to [problems with thinking and memory]. Cortical thinning seems to persist for many years after someone stops smoking," lead author Dr. Sherif Karama, an assistant professor of psychiatry at McGill University in Montreal, said in a university news release.

Low Vitamin D Levels in Stroke Survivors a Bad Sign, Study Finds

February 12, 2015 -- Low vitamin D levels are linked to an increased risk of suffering a severe stroke and poor health in stroke survivors, new research finds. The study included almost 100 stroke patients who were treated at a U.S. hospital between 2013 and 2014. All had experienced an ischemic stroke, which is a stroke caused by blocked blood flow to the brain.

People with low blood levels of vitamin D -- less than 30 nanograms per milliliter (ng/mL) -- had about two times larger areas of stroke-related dead brain tissue than those with normal vitamin D levels, according to the study. The researchers also found that for each 10 ng/mL reduction in vitamin D level, the odds of a healthy recovery in the three months after stroke fell by about half, regardless of age or initial stroke severity.

Although this study found an association between low vitamin D levels and poor stroke outcomes, it wasn't designed to show whether or not vitamin D levels actually caused any of those problems. The study was scheduled to be presented Wednesday at the American Stroke Association's annual meeting in Nashville. Findings from studies presented at meetings are generally considered preliminary until they've been published in a peer-reviewed journal.

Mediterranean Diet May Lower Stroke Risk, Study Finds

February 12, 2015 -- A Mediterranean diet may reduce your risk of one type of stroke, new research suggests. People who most closely followed the Mediterranean diet were less likely to suffer an ischemic stroke -- caused by a blood clot -- compared to people with the lowest adherence to the diet, the study found.

A Mediterranean diet includes plenty of fruits and vegetables, whole grains, legumes, nuts, fish, poultry and olive oil. There is limited consumption of red meat, sweets and saturated fats such as those in meat, butter and full-fat dairy products, according to the researchers. While the research couldn't prove cause-and-effect, "overall, there is strong evidence, based on this study, that strict adherence to a Mediterranean diet significantly reduces stroke risk,"

said Dr. Paul Wright, chair of neurology at North Shore University Hospital in Manhasset, N.Y.

Coffee Linked to Possible Lower Endometrial Cancer Risk

February 6, 2015 -- Ladies, a heavy coffee habit might do more than perk you up. New research suggests it may also reduce your risk of endometrial cancer. Using data on more than 456,000 women from two large ongoing studies, researchers evaluated the dietary habits of more than 2,800 women diagnosed with cancer of the endometrium, the lining of the uterus. Compared to women who drank less than a cup a day, those who drank about four cups daily had an 18 percent lower risk of getting this cancer, they found.

"We were not surprised by the results that a high versus low intake of coffee was associated with a reduced risk for endometrial cancer, because they were consistent with what has been observed in previous studies," said study leader Melissa Merritt. She is a research fellow in cancer epidemiology at Imperial College London in England. "We used similar methods to investigate the association between coffee intake and endometrial cancer as previous studies," she said. "This is important so we can compare results across different studies." One trial concluded 37 ounces of coffee daily reduced endometrial cancer risk by 18 percent. The other found a similar reduction associated with 26 ounces a day. The new study was published in the February issue of *Cancer Epidemiology, Biomarkers & Prevention*.

Type 1 Diabetes More Deadly for Women Than Men, Study Finds

February 5, 2015 -- Women with type 1 diabetes have a nearly 40 % greater risk of dying from any cause and more than double the risk of dying from heart disease than men with type 1 diabetes, Australian researchers report.

In an analysis of 26 studies that included more than 200,000 people, researchers found that women with type 1 diabetes had a 37 percent higher risk of dying from stroke compared to men with type 1 diabetes. The researchers also found that women with type 1 diabetes had a 44

percent greater risk of dying from kidney disease than men with type 1 diabetes.

"Type 1 diabetes increases the risk of premature death in both women and men, but type 1 diabetes is much more deadly for women than men with the condition," said lead researcher Rachel Huxley, director of the Queensland Clinical Trials and Biostatistics Center at the University of Queensland in Herston, Australia. The report was published in the Feb. 6 online edition of *The Lancet Diabetes & Endocrinology*.

New MRI Test May Help Diagnose Liver Condition in Kids

February 5, 2015 -- A new medical imaging technique can help doctors better detect non-alcoholic fatty liver disease in children, new research suggests. Five million to 8 million children in the United States have the condition, but most cases go undiagnosed, according to the University of California, San Diego researchers. Children with the disease have large droplets of fat in at least 5 percent of their liver cells. Obesity and diabetes are risk factors for non-alcoholic fatty liver disease, which can lead to hepatitis, liver scarring, cirrhosis and liver cancer. The researchers tested a new imaging method called magnitude-based MRI that might make it easier to diagnose the condition in children.

The new MRI technique was assessed in 174 children who were having liver biopsies. Depending on how it is used, magnitude-based MRI could correctly identify 65 percent to 90 percent of children as having or not having fatty liver disease, the researchers said. However, further refinements are needed before this or any other MRI technique can be used to diagnose non-alcoholic fatty liver disease in children. The study was published Feb. 5 in the journal *Hepatology*.

Smartphone Device Detects HIV, Syphilis

February 4, 2015 -- A smartphone accessory that can detect HIV and syphilis has been developed by Columbia University researchers. The low-cost device can spot markers of the infectious diseases from a finger prick of blood in 15 minutes. It's the first smartphone accessory

that replicates all the functions of a laboratory-based blood test, according to the researchers.

The device was tested by health care workers in Rwanda who used it to analyze blood samples from 96 patients. The health care workers were given 30 minutes of training on the device, and 97 percent of the patients had a positive response to the device.

The findings were published Feb. 4 in the journal *Science Translational Medicine*.

Women Use More Oxygen for Breathing

February 4, 2015 -- Muscles that control breathing require more oxygen in women than in men, a new study has found. The findings could prove important in the treatment of lung disorders, the Canadian researchers said.

They tested men and women during exercise and discovered that the muscles needed for breathing -- such as the diaphragm and those surrounding the ribcage -- consumed more oxygen in women than in men. That means that women use more energy when breathing because a greater portion of their oxygen is used by the respiratory muscles, explained the authors of the study, which was published Feb. 3 in the *Journal of Physiology*.

Major milestone for GSK/NIH candidate Ebola vaccine as first doses shipped to Liberia for use in phase III clinical trial

January 23, 2015 -- GSK has announced that the first batch of its candidate Ebola vaccine is being shipped to West Africa and is expected to arrive in Liberia later today Friday 23 January. The shipment, containing an initial 300 vials of the candidate vaccine, is the first to arrive in one of the main Ebola affected countries and will be used to start the first large-scale efficacy trial of experimental Ebola vaccines in the coming weeks.

The candidate vaccine is currently being tested in five small phase I clinical trials in the UK, USA, Switzerland and Mali, involving around 200 healthy volunteers in total. Initial data from these trials show that the candidate vaccine has an acceptable safety profile, including in a West African population, and across the different doses evaluated. Based on the safety and immunological data

available from these trials, GSK has selected the most appropriate dosage level to advance to the next phases of clinical testing. Results from the first of the phase I studies were published in November 2014 and results from the remaining phase I studies will be published in the coming months.

The selected dose will now be tested in a large phase III clinical trial led by the US National Institutes of Health (NIH) which is expected to involve up to 30,000 people, one third of whom will receive GSK's candidate Ebola vaccine. It will compare the candidate vaccine to a control vaccine to assess whether the immune response seen in phase I trials actually translates into meaningful protection against Ebola. This trial will begin in Liberia in the coming weeks, subject to regulatory approval, with further shipments of vaccines to follow.

'Glowing' new nanotechnology guides cancer surgery, also kills remaining malignant cells

January 06, 2015 -- Researchers at Oregon State University have developed a new way to selectively insert compounds into cancer cells - a system that will help surgeons identify malignant tissues and then, in combination with phototherapy, kill any remaining cancer cells after a tumor is removed.

It's about as simple as, "If it glows, cut it out." And if a few malignant cells remain, they'll soon die. The findings, published in the journal *Nanoscale*, have shown remarkable success in laboratory animals. The concept should allow more accurate surgical removal of solid tumors at the same time it eradicates any remaining cancer cells. In laboratory tests, it completely prevented cancer recurrence after phototherapy.

Technology such as this, scientists said, may have a promising future in the identification and surgical removal of malignant tumors, as well as using near-infrared light therapies that can kill remaining cancer cells, both by mild heating of them and generating reactive oxygen species that can also kill them.

Breast cancer vaccine shows promise in small clinical trial

December 01, 2014 -- A breast cancer vaccine developed at Washington University School of Medicine in St. Louis is safe in patients with metastatic breast cancer, results of an early clinical trial indicate. Preliminary evidence also suggests that the vaccine primed the patients' immune systems to attack tumor cells and helped slow the cancer's progression. The study appears Dec. 1 in *Clinical Cancer Research*.

The new vaccine causes the body's immune system to home in on a protein called mammaglobin-A, found almost exclusively in breast tissue. The protein's role in healthy tissue is unclear, but breast tumors express it at abnormally high levels, past research has shown. "Being able to target mammaglobin is exciting because it is expressed broadly in up to 80 percent of breast cancers, but not at meaningful levels in other tissues," said breast

cancer surgeon and senior author William E. Gillanders, MD, professor of surgery. "In theory, this means we could treat a large number of breast cancer patients with potentially fewer side effects.

The vaccine primes a type of white blood cell, part of the body's adaptive immune system, to seek out and destroy cells with the mammaglobin-A protein. In the smaller proportion of breast cancer patients whose tumors do not produce mammaglobin-A, this vaccine would not be effective. In the new study, 14 patients with metastatic breast cancer that expressed mammaglobin-A were vaccinated. The Phase I trial was designed mainly to assess the vaccine's safety. According to the authors, patients experienced few side effects, reporting eight events classified as mild or moderate, including rash, tenderness at the vaccination site and mild flu-like symptoms. No severe or life-threatening side effects occurred.

Sources: www.drugs.com; www.worldpharmanews.com

Information collected and compiled by:

Mr. S. M. Ashikur Rahman

Lecturer, Department of Pharmacy

State University of Bangladesh

Dhanmondi, Dhaka