

MEDICAL NEWS

- **Truvada 5 Things to Know About the First Drug to Prevent HIV**

Time Healthland (July 17, 2012) - Doctors now have another weapon against HIV/AIDS in their arsenal, and it's a potent one. For the first time, the U.S. Food and Drug Administration (FDA) approved a drug treatment that will prevent infection in healthy people.

The drug, called Truvada, which is already approved for the treatment of HIV in infected patients, works by lowering the amount of virus circulating in people's blood. But clinical trials show that it can also protect uninfected high-risk people from acquiring the virus, if they take the drug daily before and after exposure.

The approval is controversial. Some public health experts argue that allowing the drug to be used for prevention will foster a false sense of security among users, leading people to believe mistakenly that they are immune to the virus and reduce their use of condoms. However, the FDA determined that the benefits of expanding the pool of people who may use Truvada to protect against HIV made it worth approving. Here's what you need to know.

- **Who can take Truvada?**

The drug, made by Gilead Sciences Inc., is approved for healthy, uninfected people who are at high risk of contracting HIV through sex. These include sex workers and people with partners who are HIV-positive or engage in high-risk behaviors, such as using IV drugs.

- **How effective is the drug in preventing HIV?**

In one study, healthy gay and bisexual men who took Truvada daily and were counseled about safe sex practices lowered their risk of becoming infected by up to 42%. In another study involving heterosexual couples in which one partner was HIV-positive, the uninfected partner had a 75% lower risk of contracting HIV if they took Truvada.

- **Does Truvada cure AIDS?**

No. The drug can treat people who are infected with HIV by lowering the amount of virus in their bodies and slowing down the progression of the disease. In healthy, uninfected people, the drug can thwart HIV's ability to take hold in healthy cells and start an infection, by blocking the activity of an enzyme that the virus needs to replicate.

- **Why is the approval controversial?**

Some experts believe that healthy people may not take the drug correctly — it needs to be taken daily to be effective — which would encourage HIV to become resistant to the medication. Public health officials also worry that people may engage in more risky behaviors when they are on the drug, believing they are protected completely against HIV, which they are not. However, patients who receive Truvada prophylactically will be expected to participate in a comprehensive HIV protection plan involving regular HIV testing, condom use and prevention counseling and support. Clinical trials have not shown that users are more likely to engage in risky sexual behavior.

Researchers also can't explain why in one study involving female sex workers, those who took Truvada to prevent HIV were not protected against infection. The authors think that the participants did not take the drug in the right

doses, but it's also possible that something about the vaginal environment makes the drug less effective.

- **Why is the approval important?**

Approving a drug to prevent HIV marks a big step toward controlling the spread of HIV and AIDS, not just in the U.S. but worldwide as well. Public health experts are eager to build up all effective prevention strategies, noting that the only way to stop the epidemic is by preventing new infections, as well as treating existing ones.

- **Scientists closer to birth control pill for men**

ABC News (Aug. 17, 2012) Scientists may be one step closer to a birth control pill for men.

A drug dubbed JQ1 swiftly stunted sperm production in male mice, a new study found. And like the female birth control pill, its fertility-fighting effects were completely reversible.

"We have only observed full recovery of fertility in treated males," the researchers from Baylor College of Medicine wrote in their study, published today in the journal *Cell*. "We envision that our discoveries can be completely translated to men, providing a novel and efficacious strategy for a male contraceptive."

JQ1 blocks a protein essential for sperm production in the testes. If the drug is proven to be safe and effective in humans, it could expand the prophylactic pool -- an exciting prospect at a time when over a third of U.S. pregnancies are unintended.

But some doctors say the idea of slashing sperm counts, even temporarily, can be scary for guys.

"Sperm-making is a pretty delicate thing, and people do seem to have a concept of that," Dr. Joseph Alukal, director of male reproductive health at New York University's Langone Medical Center, told ABCNews.com in 2011. "How long did it take for women to get comfortable with the reversibility of the birth control pill? I'm not sure."

Nevertheless, Alukal said he thinks some men would welcome the option of a birth control pill.

"If you look at vasectomy, there are plenty of men in committed relationships who choose to take onus of reproductive planning on themselves," Alukal said. "I think the same sort of people would choose to look into something like this."

But some women are wary, saying they might not count on the male contraceptive pill alone.

"If I were dating around, though, there's no way I would trust someone that I'd been on just a few dates with [to take the pill]," 24-year-old Amy McCarthy told ABCNews.com in 2011. "I think for most men it just wouldn't be a thought that crossed their mind -- they're worried about getting HIV or gonorrhea, not having a screaming baby."

- **Many Trendy 'Microgreens' Are More Nutritious Than Their Mature Counterparts**

ScienceDaily (Aug. 29, 2012) — The first scientific analysis of nutrient levels in edible microgreens has found that many of those trendy seedlings of green vegetables and herbs have more vitamins and healthful nutrients than their fully grown counterparts.

A report on the research appears in ACS' *Journal of Agricultural and Food Chemistry*.

Qin Wang, Gene E. Lester and colleagues point out that microgreens have gained popularity as a new culinary trend over the past few years, especially in upscale markets and restaurants. Those seedlings of spinach, lettuce, red cabbage and other veggies are usually 1-3 inches in height and harvested within 14 days of germination. They enhance the color, texture and flavor of salads, soups, sandwiches and other foods. Despite their growing popularity, no scientific information existed on how nutrients in microgreens compare to those in mature plants. To fill that gap, they analyzed vitamins and other phytochemicals in 25 varieties of microgreens.

They found that microgreens generally have higher concentrations of healthful vitamins and carotenoids than their mature counterparts. But they also found wide variations in nutrient levels among the plants tested in the study. Red cabbage microgreens, for instance, had the highest concentration of vitamin C, for instance, while green daikon radish microgreens had the most vitamin E. Concentrations of vitamins and carotenoids in popcorn shoots and golden pea tendrils were low compared to other microgreens, but were still as high as some common mature vegetables.

One other notable finding: exposing microgreens to light tended to change the nutritional content, which is an ongoing research effort led by Dr. Lester and Dr. Wang, and results will be published soon.

• Stop Diabetes With Insulin Tablets?

ScienceDaily (Sep. 19, 2012) — Could a capsule of insulin crystals a day stop the development of type 1 diabetes? There are indications that this could be the case. In the international TrialNet study, which follows relatives of individuals with type 1 diabetes, researchers are investigating whether oral insulin could prevent or delay the disease.

Type 1 diabetes is the autoimmune form of diabetes, in which the patients' insulin-producing beta cells are destroyed by their own immune system. "We know that if a person has two autoantibodies and one of them is against insulin, there is a 50 per cent risk that they will develop type 1 diabetes within five years. It doesn't matter how old you are," says Åke Lernmark, Professor of Experimental Diabetes Research at Lund University in Sweden.

"There are indications that oral insulin may prevent or delay the clinical onset of type 1 diabetes among individuals with autoantibodies against insulin, who are thus in the risk zone," says Åke Lernmark, who will be initiating and coordinating the Swedish TrialNet study.

Åke Lernmark refers to a study presented earlier in the year by American and Canadian researchers. In the study, which ran from 1994 to 2003, participants with relatives who had type 1 diabetes and at least two autoantibodies, one of which against insulin, took either oral insulin or placebo capsules containing an inactive substance. At first, the results were a disappointment. Just as many people in the treatment group became ill as in the placebo group.

"However, the subsequent analyses showed something different. Among those who had high levels of insulin autoantibodies at the start of the study, the oral insulin had an effect and the development of type 1 diabetes was delayed. The delaying effect lasted for as long as the participants took the insulin," says Åke Lernmark,

adding that those who are now being recruited for the Swedish TrialNet study with oral insulin also have high levels of autoantibodies against insulin.

No one knows how oral insulin might stop type 1 diabetes. However, Åke Lernmark believes a possible explanation could be that the immune system becomes accustomed to the low daily doses of insulin in the gastrointestinal tract. The insulin is not perceived as a foreign substance to be rejected by the immune system.

This line of reasoning is the same as for desensitization for allergies, in which the dose of the substance that provokes the allergy is gradually increased.

The oral insulin study will run for several years and is open to all those who meet the requirements and are aged between 3 and 45.

• Warfarin therapy should not be stopped completely after GI bleeding

News-Medical.net (September 25, 2012) The decision to not resume warfarin therapy following a gastrointestinal bleeding (GIB) event is linked to an increased risk for thrombosis and mortality, researchers suggest.

"Our analysis suggests that, for many patients who have experienced GIB, the benefits of resuming warfarin therapy will outweigh the risks," comment Daniel Witt (Kaiser Permanente of Colorado, Aurora, USA) and co-authors in the Archives of Internal Medicine.

The retrospective cohort study found that among 442 patients with a warfarin-associated index GIB event, 260 (58.8%) patients resumed warfarin therapy within 90 days, including 41 patients whose warfarin therapy was never stopped.

During the 90-day follow-up period, 11 (2.5%) patients experienced a thrombotic event, defined as stroke, systemic embolism, pulmonary embolism, and deep vein thrombosis. Of the 260 patients who resumed warfarin therapy following the index GIB, one (0.4%) had a thrombotic event compared with 10 (5.5%) of the 182 patients who did not resume warfarin therapy.

Indeed, warfarin therapy resumption after the index GIB was associated with a 95% lower risk for thrombosis and a 69% lower risk for mortality. Moreover, in multivariate analysis adjusting for factors including age, gender, and indication for warfarin use, warfarin therapy resumption decreased the risk for subsequent thrombosis and mortality without significantly increasing the risk for recurrent GIB.

Compared with all other patients, the rate of recurrent GIB was significantly increased when warfarin therapy was resumed between 1 and 7 days after the index GIB, at 6.23 versus 12.4%.

In addition, compared with all other patients, the death rate during the 90-day follow up was lowest (2.3%) when warfarin therapy was resumed between 15 and 90 days after the index GIB.

"A better understanding of the propensity for recurrent hemorrhage and its severity across the spectrum of anatomic lesions would help to inform the decision of optimal timing of anticoagulation resumption, an issue of major importance for individuals at highest risk of thromboembolism," remark the authors.