Department of Pharmacy

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# PHARMA HIGHLIGHTS

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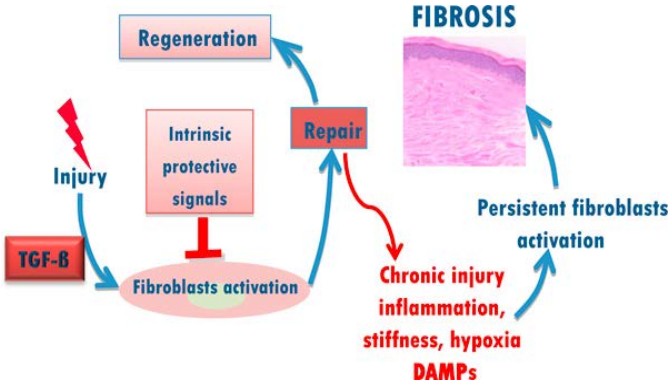
## Drug Combination Halts the Progression of Fibrosis




Fibrosis may refer to the connective tissue deposition that occurs as part of normal healing or to the excess tissue deposition that occurs as a pathological process. When fibrosis occurs in response to injury, the term “scarring” is used. It is an exaggerated wound healing response which interferes with normal organ function.

Fibrosis starts when injury induces fibroblast cells to convert into myofibroblast for wound healing. Normally, after healing, the tissue returns to its normal structure (before injury). However, the process is exaggerated in fibrosis as the myofibroblasts go out of control and 'over heal' forming scar tissue. Scar tissue is dead tissue and hold no biological function. If scarring occurs in major organs such as kidney, lungs, liver or heart it can interferes with normal organ function.

A collaborative research effort from Anglia Ruskin University, University College London and KU Leuven—lead to the innovating drug combination that can potentially to stop the progression of Fibrosis. The scientists started by testing 21 different drugs to treat a disease called Peyronie's Disease (development of fibrous scar tissue inside the penis).

After testing on cells and animal models, they identified that combining phosphodiesterase type 5 inhibitors (vardenafil, sildenafil, tadalafil) with selective estrogen receptor modulators (tamoxifen or raloxifene) could be used to halt the progression of fibrosis that causes Peyronie's Disease.

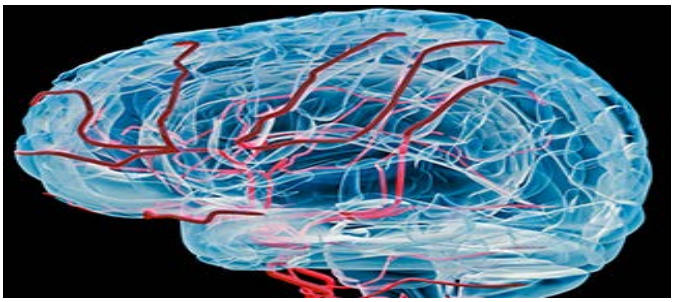
Although this drug combination will not able to reverse the fibrotic process, it has the potential to treat all fibrotic diseases and halt progression. This is an important breakthrough and one that has taken seven years of research.

This is the first study of its kind to show that a drug combination is effective in halting the progression of fibrosis. The scientists plan to take novel combination to clinical trials soon.

Source: European Urology, Science Daily

## Stroke Doubles Risk of Dementia

Stroke refers to the blockage of cerebral arteries leading to deprivation of oxygen and other essential nutrients and eventually cell death. This causes irreversible damage, even if the blood flow is restored. It is the second most common cause of death worldwide. It is often followed by complications, such as infections and blindness and dementia. Dementia is a disorder which is characterized by decline in cognitive functions, affecting 47 million people worldwide. Although previous studies have established a relationship between stroke and dementia, a recent study Dr. David Llewellyn and colleagues at



University of Exeter Medical School wanted to quantify the extent to which stroke increased the risk of dementia. They analyzed the data of people in risk of stroke and dementia worldwide. It was found that the relationship between stroke and dementia existed even when factors such as blood pressure, diabetes, and cardiovascular disease were taken into account. Interestingly, the risk of dementia increased to 70%, if a person already had a stroke. Studies in the near future will hopefully take into account factors such as ethnicity, education, post stroke care, and lifestyle as well. Further research is warranted for post-stroke care, since it may play an important role in developing dementia.

Dr. Llewellyn believes that around a third of all dementia cases (including those associated with stroke) are preventable. Their findings reinforce the importance of a healthy blood supply to the brain which could potentially reduce the global burden of dementia.

Source: Alzheimer’s & Dementia, Stroke Center, Mayo Clinic, WHO

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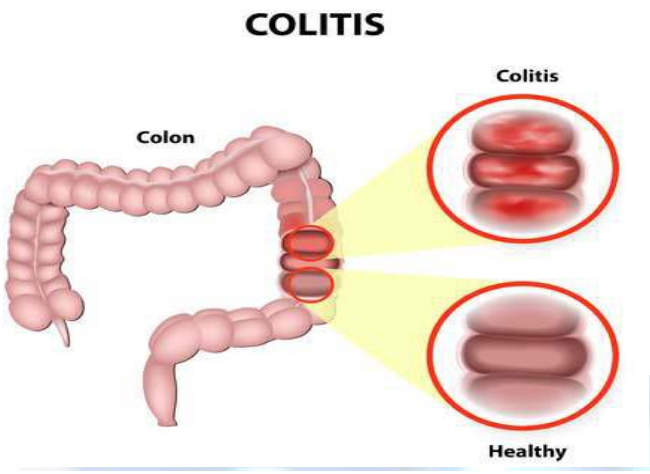
## Insulin May Be A New Colitis Treatment




Insulin is a hormone made by the pancreas which keeps blood sugar levels from becoming too high. It is usually used in the treatment of diabetes, but researchers at University of Copenhagen and Roskilde University have shown that it could also be useful in the treatment of ulcerative colitis by reducing bowel inflammation in mouse model.

Ulcerative colitis is a disorder of the large intestine (colon) which causes inflammation, aching and cramping, bloody diarrhea, anemia, and weight loss. Existing treatments involve drugs that suppress the immune system which is responsible for initiating the inflammation. However, the patient still suffers from significant loss of weight. Using insulin scientists found a way to strengthen the large intestine's cells defenses and retain weight. After assessing their mouse model, the scientists found that in mice that received the insulin treatment, fifteen to twenty percent less weight was lost and they were able to gain weight fifty percent faster.

Further gene expression studies revealed that insulin reduces the expression of COX-2 gene (inflammatory marker), suggesting it may play role in reducing inflammation. The current hypothesis is that insulin acts by activating an antioxidant gene which may also act as a guard against inflammation. Since the existing treatments act via a different mechanism by affecting the immune system, it may be possible to combine the two treatments. The researchers are at University of Copenhagen and Roskilde University are trying to bring this treatment from bench to bedside by filing a patent and forming a startup business that will carry out the necessary clinical trials.

Source: AAAS/Eurekalert! via University of Copenhagen, Journal of Crohn's and Colitis

## FDA Approves New Drug For Mycobacterial Lung Disease

The U.S. Food and Drug Administration approved a new drug, Arikayce, for the treatment of lung disease caused by the *Mycobacterium avium* bacteria complex. This drug will be provided to those patients with the disease who do not respond to conventional treatments. The FDA granted approval of Arikayce to Insmed Inc.

Arikayce became the first drug to be approved under the FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LAPD), which allows approval antibacterial and antifungal drugs to treat serious or life-threatening infections in a limited population of patients with unmet need. The FDA also granted this application Accelerated and Orphan Drug designations, which allows the fast-track development of drugs for rare diseases.

The approval of Arikayce was based on achieving three consecutive negative monthly sputum cultures by month six of treatment. The safety and efficacy of Arikayce, an inhaled treatment taken through a nebulizer, was demonstrated in a randomized, controlled clinical trial where patients were assigned to one of two treatment groups. One group of patients received Arikayce plus a background multi-drug antibacterial regimen, while the other treatment group received a background multi-drug antibacterial regimen alone. By the sixth month of treatment, 29 percent of patients treated with Arikayce had no growth of mycobacteria in their sputum cultures for three consecutive months compared to 9 percent of patients who were not treated with Arikayce.

Additionally, the Arikayce prescribing information includes a Boxed Warning regarding the increased risk of certain respiratory conditions.


Source: fda.gov