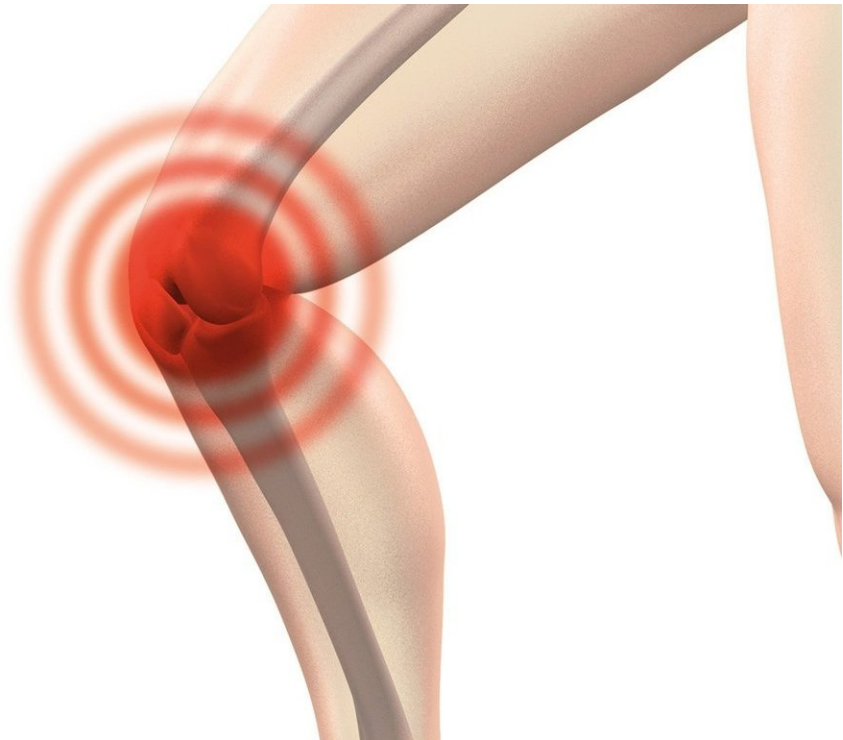


Experimental growth factor shows promise for treating knee osteoarthritis

October 8 2019



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More than 10 percent of Americans over age 60 experience knee pain related to osteoarthritis, the most common disease of the knee joint. Osteoarthritis of the knee causes pain, activity limitation, physical disability, reduced health-related quality of life and excess mortality compared with the general population. The pain is usually treated with

over-the-counter pain relievers, anti-inflammatory drugs, local steroid injections and sometimes surgery. There are currently no drugs approved to treat the underlying cause of the condition, which results from the breakdown of joint cartilage covering the long bones due to increasing age, injury/overuse, obesity, genetics and/or local inflammation. A new experimental growth factor therapy, however, appears to prevent a worsening of osteoarthritis by increasing the thickness of cartilage in the knee joint and preventing further loss, according to results from an early clinical trial that were published today in the *Journal of the American Medical Association*.

The study, led by researchers at the University of Maryland School of Medicine (UMSOM), involved 549 volunteers with knee osteoarthritis who were randomly assigned to get injections of the drug sprifermin, recombinant human fibroblast growth factor 18, either at a low dose of 30 micrograms (μg) or a high dose of 100 μg , either once or twice a year, or assigned to get placebo injections. The researchers found that those who received a 100 μg dose either twice or once yearly experienced a statistically significant but slight gain in joint cartilage thickness after two years as measured on quantitative magnetic resonance imaging (MRI), a gain of 0.03 or 0.02 millimeters (mm) compared to the [placebo group](#) that lost 0.02 mm of cartilage during the two-year period. Those given smaller doses had smaller gains in cartilage; indeed, the gains in the lower dose groups were not deemed to be statistically or clinically significant.

Patients treated with the higher dose of sprifermin, however, did not experience any significant improvement in their arthritis symptoms—including pain, stiffness, and physical dysfunction like walking difficulties—compared to those given the lower dose or those given placebo injections.

"While the increase in cartilage thickness is a positive sign, we do not

know at this point whether it has any clinical significance," said study lead investigator Marc Hochberg, MD, MPH a Professor of Medicine at UMSOM. "It is not known whether those who experience increased cartilage thickness over time will be able to avoid or delay knee replacement surgery."

While injections were stopped after 18 months, the analyses showed that the difference between groups that received the higher dose of sprifermin and placebo persisted out to three years. The study was designed to continue for a total of five years and future analyses of the entire trial dataset are planned.

In a more recent post-hoc analysis of the data, Dr. Hochberg and his colleagues evaluated a subgroup of osteoarthritis patients with severe pain and narrow joint space in their knee who were at higher risk of disease progression; they found that those in the group who received sprifermin 100µg every six months experienced significant improvements in their arthritis symptoms 18 months after their last [injection](#) compared to those who received placebo injections. "These results support further investigation of sprifermin as a potential osteoarthritis treatment for both structure modification and symptom relief for higher-risk patient populations," Dr. Hochberg said. These results were presented in June at the European Congress of Rheumatology's annual meeting,

"Finding an effective therapy that can treat the cause of common chronic pain conditions like osteoarthritis would be a ground-breaking achievement," said E. Albert Reece, MD, Ph.D., MBA, Executive Vice President for Medical Affairs, UM Baltimore, and the John Z. and Akiko K. Bowers Distinguished Professor and Dean, University of Maryland School of Medicine. "I'm proud that our scientists are helping to move the knowledge forward on the effectiveness of new therapies to replace worn [cartilage](#) in the joints. This is very important work, and

more answers are certainly needed."

Side effects associated with the use of sprifermin were mostly mild or moderate and consisted mainly of acute inflammatory reactions ([pain](#), redness, swelling) at the site of the injections. The study was funded by Merck KGaA, manufacturer of sprifermin, located in Darmstadt, Germany.

More information: *Journal of the American Medical Association* (2019). [DOI: 10.1001/jama.2019.14735](https://doi.org/10.1001/jama.2019.14735)

Provided by University of Maryland School of Medicine

Citation: Experimental growth factor shows promise for treating knee osteoarthritis (2019, October 8) retrieved 23 April 2024 from <https://medicalxpress.com/news/2019-10-experimental-growth-factor-knee-osteoarthritis.html>

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