

Aspirin as effective as blood thinner injections to prevent deadly complications in patients with bone fractures

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Patients hospitalized with fractures typically receive an injectable blood thinner, low-molecular-weight heparin, to prevent life-threatening blood clots. A new clinical trial, however, found that inexpensive over-the-

counter aspirin is just as effective. The findings, published today in the *New England Journal of Medicine*, may lead surgeons to change their practice and administer aspirin to these patients.

The multi-center randomized clinical trial, which included more than 12,000 patients at 21 trauma centers in the U.S. and Canada, is the largest trial ever conducted on orthopedic trauma patients. This multidisciplinary collaboration between orthopedic surgeons and trauma surgeons points to the importance of evaluating techniques used to prevent post-surgical complications, like [blood clots](#) and infections, through high-quality, head-to-head comparison studies.

The trial was co-led by the Department of Orthopaedics at the University of Maryland School of Medicine (UMSOM) and the Major Extremity Trauma Research Consortium (METRC) based at the Johns Hopkins Bloomberg School of Public Health.

"Many patients with fractures will likely strongly prefer to take a daily [aspirin](#) over receiving injections after we found that both give them similar outcomes for prevention of the most serious outcomes from blood clots," said the study's principal investigator Robert V. O'Toole, MD, the Hansjörg Wyss Medical Foundation Endowed Professor in Orthopaedic Trauma at UMSOM and Chief of Orthopaedics at the R Adams Cowley Shock Trauma Center at the University of Maryland Medical Center (UMMC). "We expect our findings from this large-scale trial to have an important impact on [clinical practice](#) that may even alter the standard of care."

Blood clots cause as many as 100,000 deaths in the U.S. each year, according to the U.S. Centers for Disease Control (CDC). Patients who experience fractures that require surgery are at increased risk of developing blood clots in the lungs and limbs. Large clots in the lungs even can be life-threatening. Current guidelines recommend prescribing

low-molecular-weight heparin (enoxaparin) to prevent these clots, although smaller clinical trials in total joint replacement surgery suggested a potential benefit of aspirin as a less-expensive, widely available option.

The study enrolled 12,211 patients with leg or arm fractures that necessitated surgery or pelvic fractures regardless of the treatment. Half were randomly assigned to receive 30 mg. of injectable low molecular-weight heparin twice daily. The other half received 81 mg. of aspirin twice daily. Patients were followed for 90 days to measure [health outcomes](#) from the two treatments.

The main finding of the study was that aspirin was "non-inferior," or no worse than low molecular-weight heparin in preventing death from any cause—47 patients in the aspirin group died, compared with 45 patients in the heparin group. For other important complications, the researchers also found no differences between the two groups in clots in the lungs (pulmonary embolisms). The incidence of bleeding complications, infection, wound problems, and other adverse events from the treatments was also similar in both groups.

Of all the outcomes studied, the only potential difference noted was in blood clots in the legs, called deep vein thrombosis. This condition was relatively uncommon in both groups as it occurred in 2.5 percent of patients in the aspirin group, and in 1.7 percent of patients in the heparin group.

"This relatively small difference was driven by clots lower in the leg, which are thought to be of less clinical significance and often do not require treatment," said study co-principal investigator Deborah Stein, MD, MPH, Professor of Surgery at UMSOM and Director of Adult Critical Care Services at UMMC.

The \$11.7 million study was funded by the Patient-Centered Outcomes Research Institute (PCORI), (PCS-1511-32745), an independent, non-profit organization that funds comparative clinical effectiveness research to help patients and clinicians make better-informed healthcare decisions.

"This large multicenter study was needed to adequately measure the impact of prophylaxis on the infrequent, but important, outcome of death that is of utmost importance to patients," said study methods center principal investigator Renan Castillo, Ph.D., Professor of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health.

The trial was called PREVENTion of CLots in Orthopaedic Trauma, or PREVENT CLOT. Patients enrolled in the trial were treated at the R Adams Cowley Shock Trauma Center at UMMC and 20 other [trauma centers](#) in 15 other states, as well as two in Canada. Recruitment started in April 2017 and continued through 2021.

"Many patients don't like giving themselves injections. It's not fun in terms of giving the actual injection because it burns, and your stomach tends to bruise more easily compared to aspirin," said Debra Marvel, a 53-year-old from Columbia, MD, who served as a patient advisor on the study. She received Lovenox (low-molecular-weight heparin) after her legs were crushed in a 2015 pedestrian accident, requiring multiple surgeries at the University of Maryland Shock Trauma Center. "Patients also prefer aspirin because Lovenox can be expensive based on insurance."

"An estimated one million Americans are hospitalized each year with extremity fractures, and this new finding could help prevent potentially fatal blood clots in these patients using a medication that is cheaper and far easier to administer," said Mark T. Gladwin, MD, Vice President for

Medical Affairs, University of Maryland, Baltimore, and the John Z. and Akiko K. Bowers Distinguished Professor and Dean, University of Maryland School of Medicine. "Given these important results, we can expect the guidelines for the prevention of blood clots to be revised to include the option of aspirin for patients with traumatic bone fractures."

More information: Aspirin or Low-Molecular-Weight Heparin for Thromboprophylaxis after a Fracture, *New England Journal of Medicine* (2023). [DOI: 10.1056/NEJMoa2205973](https://doi.org/10.1056/NEJMoa2205973)

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