

Denosumab increases bone density, cuts fracture risk in prostate cancer survivors

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Twice-yearly treatment with denosumab, a new targeted therapy to stop bone loss, increased bone density and prevented spinal fractures in men receiving androgen-deprivation therapy for prostate cancer. The report from an international research study, the first to document reduced fracture risk in men receiving the hormone-blocking treatment, will appear in the August 20 *New England Journal of Medicine* and is receiving early online release.

"Androgen-deprivation therapy is the standard treatment for men with locally advanced, recurrent and metastatic prostate cancer; but many active men who have been successfully treated for their cancer develop debilitating [bone fractures](#) as a result," says Matthew Smith, MD, PhD, of the Massachusetts General Hospital (MGH) Cancer Center, who led the study as part of the Denosumab HALT Prostate Cancer Study Group. "The results of this study should be critically important in improving the quality of life of thousands of prostate cancer survivors."

About one third of the two million prostate cancer survivors in the U.S. currently receive androgen-deprivation therapy, which blocks the release of testosterone. Several medications used to treat osteoporosis, including the drugs called [bisphosphonates](#), have been shown to reduce androgen-deprivation-related bone loss in men in earlier small clinical studies, but none of those trials were adequate to demonstrate reduced fracture risk. Denosumab - a fully human monoclonal antibody that blocks the action of osteoclasts, the cells that break down bone in the normal process of bone remodeling - is also being investigated to prevent fractures in women with osteoporosis. The current study was a Phase 3 trial supporting the application for FDA approval filed by Amgen Inc., the primary sponsor of the NEJM report.

Men undergoing androgen-deprivation therapy for nonmetastatic prostate cancer were enrolled at

156 centers in North America and Europe and randomly assigned to receive injections of either denosumab or a placebo every six months for three years. Participants were also instructed to take daily calcium and vitamin D supplements during the study period.

Among the more than 900 participants who completed the study, denosumab significantly increased bone density at all the monitored sites - including the lumbar spine, total hip and femoral neck - and reduced new vertebral fractures by 62 percent. [Bone density](#) at the radius, one of the bones in the forearm, also increased in the treatment group, an improvement not seen with other osteoporosis drugs. Few adverse events were associated with treatment, and there were no reports of osteonecrosis of the jaw, a problem reported in some patients taking bisphosphonates.

"Denosumab is an important new therapy to prevent painful fractures in prostate cancer survivors," Smith says. "An ongoing clinical trial will also evaluate whether denosumab prevents spread of [prostate cancer](#) to [bone](#), the most common site of metastases in men with this disease." Smith is an associate professor of Medicine at Harvard Medical School.

Source: Massachusetts General Hospital ([news](#) : [web](#))

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