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Role of vitamin D3 in treatment of lumbar disc herniation-Pain and sensory aspects: Study protocol for a randomized controlled trial

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Vitamin D receptors have been identified in the spinal cord, nerve roots, dorsal root ganglia and glial cells, and its genetic polymorphism association with the development of lumbar disc degeneration and herniation has been documented. Metabolic effects of active vitamin D metabolites in the nucleus pulposus and annulus fibrosus cells have been studied. Lumbar disc herniation is a process that involves immune and inflammatory cells and processes that are targets for immune regulatory actions of vitamin D as a neurosteroid hormone. In addition to vitamin D's immune modulatory properties, its receptors have been identified in skeletal muscles. It also affects sensory neurons to modulate pain. In this study, we aim to study the role of vitamin D3 in discogenic pain and related sensory deficits. Additionally, we will address how post-treatment 25-hydroxy vitamin D3 level influences pain and sensory deficits severity. The cut-off value for serum 25hydroxy vitamin D3 that would be efficacious in improving pain and sensory deficits in lumbar disc herniation will also be studied.

Methods/Design: We will conduct a randomized, placebo-controlled, double-blind clinical trial. Our study population will include 380 cases with one-level and unilateral lumbar disc herniation with duration of discogenic pain less than 8 weeks. Individuals who do not have any contraindications, will be divided into three groups based on serum 25-hydroxy vitamin D3 level, and each group will be randomized to receive either a single-dose 300,000 IU intramuscular injection of vitamin D3 or placebo. All patients will be under conservative treatment. Pre-treatment and post-treatment assessments will be performed with the McGill Pain Questionnaire and a visual analogue scale. For the 15-day duration of this study, questionnaires will be filled out during telephone interviews every 3 days (a total of five times). The initial and final interviews will be scheduled at our clinic. After 15 days, serum 25-hydroxy vitamin D3 levels will be measured for those who have received vitamin D3 (190 individuals).

Trial Registration: Iranian Registry for Clinical Trials ID: IRCT2014050317534N1 (trial registration: 5 June 2014).

Biography

Mahsa Sedighi graduated in Aug 2013 from Shiraz University of Medical Sciences, Shiraz, Iran (MD) with excellent marks. She has been an active member of research committees affiliated with Shiraz medical University. Currently she is a clinical researcher.

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