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HYPERTENSION

Pulsed electromagnetic fields for postmenopausal osteoporosis and concomitant lumbar osteoarthritis in southwest China using proximal femur bone mineral density as the primary endpoint: study protocol for a randomized controlled trial.

HYPERTENSION



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BACKGROUND: Osteoporosis (OP) and osteoarthritis (OA) are prevalent skeletal disorders among postmenopausal women. Coexistence is common especially that of postmenopausal osteoporosis (PMO) and lumbar OA. An hypothesis has been raised that OP and OA might share the same pathogenic mechanism, and pulsed electromagnetic fields (PEMFs) were reported to have anti-osteoporosis and anti-osteoarthritis properties, but this suggestion was based primarily on biomarker data. Therefore, whether these two effects could take place simultaneously has not yet been investigated. This randomized controlled trial (RCT) is designed to explore the effect of PEMFs for PMO and concomitant lumbar OA.

METHODS/DESIGN: The study will include PMO patients (postmenopausal women; aged between 50 and 70 years; have been postmenopausal for at least 5 years and diagnosed with OP using proximal femur T-score) with concomitant lumbar OA (patients with confounding disorders like diabetes, hypertension, hyperlipidemia, and previous fracture history, etcetera, will be excluded) will be randomly assigned to two arms: PEMFs group and sham PEMFs group. There will be 25 participants in each arm (50 in total) and the outcome assessment, including the primary endpoint (proximal femur bone mineral density), will be performed at 5 weeks, 3 months and 6 months after enrollment.

DISCUSSION: PMO and lumbar OA are prominent public health problem, especially for postmenopausal women. We hope this RCT will provide scientific evidence to primary care of the postmenopausal women regarding the use of these nonpharmaceutical, noninvasive modalities, PEMFs, in managing PMO and lumbar OA.

TRIAL REGISTRATION: Chinese Clinical Trial Registry: ChiCTR-TRC-14005156 (28

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