The efficacy and safety of herbal medicine BHH10 in postmenopausal women with osteoporosis: A phase II, multicenter, randomised, double-blinded, placebo-controlled clinical trial protocol

Seunghoon Lee
Kyung Hee University, South Korea

Osteoporosis is more prevalent in an aging society and the economic burden due to osteoporotic fractures is substantial. Existing osteoporosis drugs also have many uncomfortable side effects and the development of safe and highly effective treatments is a matter of some urgency. This study aims to evaluate the efficacy and safety of BHH10, a Korean traditional herbal medicine, for postmenopausal women with osteoporosis. This is a phase II, multicenter, randomised, double-blinded, placebo-controlled clinical trial and will include 168 postmenopausal women aged 55 years and older with osteoporosis. Participants will be assigned randomly to one of two groups, the BHH10 group or the placebo group, in a 1:1 ratio. Participants will take two tablets of BHH10 or placebo three times per day for 12 weeks. The change in bone mineral density (L1-4) from baseline (visit 1) to 12 weeks after randomisation (visit 5) will be determined as the primary efficacy outcome. Other outcomes include bone turnover markers, a questionnaire concerning the deficiency syndrome of the kidney index, the EuroQol questionnaire, adverse events, and laboratory tests. This is the first clinical trial to explore the efficacy and safety of BHH10 in postmenopausal women with osteoporosis. The results will be helpful for the development of Korean traditional herbal medicines for postmenopausal women with osteoporosis. If the superiority of BHH10 versus the placebo is demonstrated, this study could form the foundation for a phase III clinical trial. These results will be published in a peer-reviewed journal.

Biography

Seunghoon Lee is Korean Medical Doctor and has completed his PhD from Kyung Hee University in 2014. He is clinical assisstant professor of Kyung Hee University Korean Medicine Hospital. He has published more than 20 papers in SCI/E journals.

kmdoctorlee@gmail.com