

New drugs for osteoporosis treatment: Systematic review of clinical trials of phase II and III

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Osteoporosis is a disease characterized by decreased bone mass and deterioration of bone microarchitecture. It is a highly prevalent condition in western countries, and it is estimated to affect 5 % of the Portuguese population. Advances in the research in the pathophysiology of the disease have been used for the development of new molecules. In addition, several clinical trials have been developed in order to determine the effectiveness of new drugs to treat osteoporosis.

The aim of this study was to systematically review randomized controlled trials of oral drugs for osteoporosis treatment. The systematic review was performed in electronic databases, particularly at Clinical- Trials (www.clinicaltrials.gov) and PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>), of which were selected only clinical trials of phase II and III, in patients of female gender, published in the last five years, which addressed any drug for the treatment of osteoporosis.

After inclusion and exclusion criteria, of the 132 studies, 34 were selected to be included in the systematic review. These trials included drugs of different pharmacologic profiles. Regarding drugs with anabolic effects, molecules which stimulate bone formation, clinical trials show efficacy for Romosozumab and BA 058, while for MK-5442 the results were unsatisfactory. Regarding bone antiresorptive drugs, Denosumab was reported in several studies to have high efficacy. Other further promising drugs included ONO-5334 and Odanacatib, which showed positive results in several clinical trials.

Despite the wide diversity of drugs under clinical trials, new pharmacological options should be developed to revert bone loss in this highly prevalent chronic disease.

Keywords Osteoporosis, drugs, clinical trials, bone mineral density