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Method for the determination of the risk of atypical fractures in patients treated with bone remodelling inhibitors

The present invention relates to a method for detecting the genetically transmitted risk of atypical fractures in patients suffering bone diseases treated with inhibitors of bone remodelling or that are eligible for treatment with such drugs.

An offer for Patent Licensing and/or R+D collaboration

Genetic risk assessment of atypical fractures

Bisphosphonates are currently considered first choice treatment of osteoporosis. Its proven anti-fracture effect in all types of osteoporosis and its presence on the market for many years make them the most widely used drugs for the treatment of this disease. However, a number of adverse effects is associated with this medication such as atypical fracture. These fractures that share a number of common clinical features, do not meet the classic profile of osteoporotic fragility fractures. The risk to suffer atypical fractures is related to long-term treatment with bisphosphonates or other bone remodelling inhibitors. This has caused concerns on whether to maintain a continued treatment with these drugs, or other antiresorptive agents such as denosumab, over a long period of time. The invention makes use of a biomarker for determining the risk of developing these atypical fractures.

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Main advantages and applications

Increasingly over recent years, the diagnostic process has become more strongly driven by the need to pre-select patients based on drug labels and licenses. Therefore, most physicians are already used to the role of diagnostic tests to clarify and support their clinical decision-making. The demand for diagnostics detecting genomic or gene expression markers to accompany therapies is growing.

The sharpening focus on biomarker testing by the regulatory sector is highlighted by the growing number of drugs with this information in their labels. Pharmacogenomic information is currently contained in approximately 10% of labels for drugs approved by the FDA and, interestingly, the FDA has recently started publishing a table of genomic biomarkers that it considers valid in guiding the clinical use of approved drugs.

Being able to present reliable biomarkers for reducing adverse effects of prolonged clinical use of bisphosphonates, might induce regulatory pressure towards a standard diagnostic use in osteoporosis patients.

The invention is planned to be used in an in-vitro diagnostic tool for the determination of the risk of the stated atypical fractures in patients treated, or to be treated, with bone remodelling inhibitors. The invention could be developed towards an individual in-vitro diagnostic or, more likely, the biomarker be used in a development of multiple biomarkers into a combined in-vitro diagnostic.

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