RESEARCH TOPIC CLI28

Effects of bisphosponates and denosumab on vascular end-points and their correlation with skeletal health in subjects with type 2 diabetes mellitus: the two faces project

Clinical Unit name

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Abstract

There is a clinical interest in understanding whether and how chronic treatment of osteoporosis with bone-active drugs might influence the cardiovascular (CV) end-points of subjects with skeletal fragility and high CV risk. In vivo and in vitro investigations highlighted the existence of a cross-talking between bone remodelling and CV system. Diabetes mellitus is a unique clinical model to study the relationship between skeleton and CV system, since deregulation of glucose homeostasis is frequently associated with both skeletal fragility and high CV risk. Moreover, vascular complications of diabetes could contribute to skeletal fragility and high risk of fractures. The primary aim of this prospective project is to evaluate the effects of bone-active drugs inhibiting bone resorption [i.e, bisphosphonates (BPs) and denosumab (DEN)] on microvascular complications of patients with diabetes. As exploratory end-points the project will evaluate: 1) effects of BPs and DEN on carotid atherosclerosis; 2) changes in metabolomic fingerprints linking bone to CV health before and after treatment with anti-resorptive drugs; 3) Effects of BPs and DEN on intestinal microbiota and their relationship with cardiovascular and skeletal end-points; 4) socio-economic impact deriving from double effects of anti-osteoporotic drugs. To meet the study aims, 100 subjects with type 2 diabetes and osteoporosis with indication to treatment with BPs or DEN according to current guidelines will be enrolled (Group A). One-hundred diabetic subjects matched for age and sex and without indication to anti-osteoporotic therapies will be enrolled as controls (Group B). The enrolment will be performed in 15 months and the following analysis will be perfomed in 21 months (duration of the project 36 months).

Scientific references

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