Aim of the Project

The HORIZON 2020 project PoCOsteo (<u>Point-of-care in-office device for identifying</u> individuals at high risk of <u>Osteo</u>porosis and osteoporotic fracture; Proposal number 767325) aims to develop two different point-of-care in-vitro devices which would measure and/or quantify **proteomic and genomic factors** as present in human whole blood, with the overall goal to **improve early detection of fragile bone and to facilitate treatment monitoring**.

In order to improve the predictive value of existing fracture risk assessment models, a clinical data derivation cohort is built up in parallel, and the improved model will be integrated into the software model developed together with the to be developed invitro devices.

Inclusion / Exclusion criteria

The clinical cohort includes all **male and female patients fifty years and above** who are referred to the osteoporosis clinic of the Division of Endocrinology and Diabetology (Department of Internal Medicine) and who give their written informed consent, according to the Declaration of Helsinki and national regulations. Thus, the spectrum of objects will range from those who are healthy per definition to those who experienced multiple fragility fractures due to secondary osteoporosis. In other words, the cohort will include untreated patients as well as those treated for osteoporosis, with or without concomitant diseases such as hypertension, diabetes etc.

Dataset / Parameters

The following patient characteristics will be collected at study inclusion and after 12 months, with a possible extension up to 24 months: a comprehensive history, bone mineral density (BMD) of the hip and the lumbar spine as well as vertebral fracture assessment (VFA) by Dual X-ray absorptiometry (DXA), grip strength (hydraulic hand dynamometer), and a routine blood test including renal and hepatic parameters together with a lipid profile. In a smaller subcohort, consisting of healthy patients and those who experienced at least one fragility fracture, high resolution peripheral quantitative computed tomography (HR-pQCT; XTreme CTII) will be performed in addition.

Samples / Material

Starting in May 2018, samples from 1000 probands will be collected. The biobank specimen comprise **serum**, **EDTA-plasma** and **buffy coat** which are stored at -80°C.

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Horizon 2020 European Union funding for Research & Innovation

