Objective

Goals: We will carry out a regenerative medicine clinical trial of the therapeutic system OSTEOGROW for regenerating bone through harnessing a novel bone regenerative product to accelerate and enhance bone repair.

The osteogenic regenerative product is composed of an autologous carrier and a biologically active recombinant human protein offering a therapeutic solution in bone regeneration superior to currently available options.

The autologous carrier is a whole blood coagulum derived (WBCD) from the peripheral blood of a patient, which will act as an endogenous biocompatible material causing significantly less inflammatory reactions than currently used bone devices.

The bone inducing molecule is the recombinant human bone morphogenetic protein 6 (rhBMP6) which binds to WBCD and is more potent than other BMPs in stimulating bone formation in preclinical animal models. The consortium members will scale-up the production of rhBMP6 from an already developed working cell bank to enter clinical trials on bone regeneration.
The bone diseases we will treat locally with OSTEOGROW are acute radius fractures and healing of distraction gap in high tibial osteotomy (HTO). These conditions are widespread and highly debilitating diseases for which such therapy holds great promise.

Workflow: Preliminary pre-clinical data are already available, and clinical grade (GMP) rhBMP6 will be available before the beginning of the project to perform toxicology studies and to determine the final formulation of OSTEOGROW. Clinical trials will start within 18 months from the start of the project funding.

Business strategy: SMEs Genera Research, Vitrology Limited and Meditox will test and validate the rhBMP6 production in their facilities. Consortium members from Medical University of Vienna, Sarajevo University Clinical Centre, Linkoping University Faculty of Health Sciences, Zagreb University Trauma Clinic, SMART Medico and Paul Regulatory Services will perform, monitor and coordinate clinical trials. OSTEOGROW will find a wide use in human and veterinary medicine.

Field of Science

/medical and health sciences/health sciences
/agricultural sciences/veterinary science
/social sciences/economics and business
/social sciences/sociology/governance/public services
/medical and health sciences/basic medicine/toxicology

Programme(s)

FP7-HEALTH - Specific Programme "Cooperation": Health

Topic(s)

HEALTH.2011.1.4-1 - Regenerative medicine clinical trials

Call for proposal

FP7-HEALTH-2011-two-stage

See other projects for this call

Funding Scheme

CP-FP - Small or medium-scale focused research project

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Permalink: https://cordis.europa.eu/project/id/279239/en