P521	New bone graft for treatment of acetabular bone loss in human: Association of expanded MSC and rhBMP-7 - Preliminar results	Burastero, G.; Grappiolo, G.; Podestà, M.; Sessarego, N.; Frassoni, F.; Spotorno, L.

We aim to treat periprosthetic bone defects after THA with a bone graft made up of the association of human expanded MSC plus rhBMP-7.

Materials and methods
This study, has been approved as phase 1, by the Istituto Superiore Sanità, reference number 46575-Pre-21-862. The study is a pilot, prospectic, non randomized study recruiting up to 30 patients. Primary endpoint is to investigate the optimal therapeutic dose by evaluation of the safety of the association of expMSC and rhBMP-7 and report Serious Adverse Event or Adverse Events during the study. Secondary endpoint is to test the efficacy of bone graft. Eligible subjects for the study must apply all the following criteria: scheduled for elective revision hip surgery, written informed consent has been obtained, periprosthetic bone loss with Paprosky >= II . One month before the revision surgery, 250-300 ml of BM will be harvested from posterior iliac crest of the patient. The BM will be sent to cell therapy unit for isolation and ex vivo expansion of hMSC. At the beginning and at the end of the cell expansion procedure, quality and safe tests will be performed. All steps of the isolation and expansion process will follow current GMP guide lines. Moreover, clinical scale expansion of the autologous hMSC will be carry on up to the third passage, in order to reduce risks of karyotype alterations. The bone graft will be composed of inorganic matrix Orthoss (Geistlisch, Ch) and Calstrux (Stryker, USA), ex vivo expanded MSC, rh-BMP-7 (Stryker, USA). We will use dosage of different components per unit (cm3) of bone defect, determined by CT scan.When the graft is ready, the patient will be subjected to revision surgery and the graft positioned. Before the graft implant and at the moment of graft positioning, microbiological analysis will be performed to verify the sterility of the final cell therapy product. Graft evolution will be documented by radiographic and TC analysis at different follow up time points.

Results and discussion
To date one subject has been enrolled with 3 months of follow up. So that our results are preliminary. Serious adverse events did not happen and an encouraging radiographic pattern of the osseous graft was observed. Until now clinical studies that apply the combined use of exp MSC and rhBMP-7 has not been reported in literature. Small osseous defects can be treated efficacly with other bone graft transplant techniques, but massive osseous defects should be treated with a bone graft including: a inorganic component with a osteoconductive and refilling functions, a component endowed of high osteoinductive action such as rhBMP7, autologous component with high osteogenetic capacity such as exp-MSC. Remain to be considered the application of GMP procedure and the high cost of this tecnique.