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Title: NEW-ONSET DIABETES MELLITUS AFTER RENAL TRANSPLANTATION. A MULTICENTRE, PROSPECTIVE, RANDOMIZED, OPEN STUDY TO EVALUATE BELATACEPT-BASED VERSUS TACROLIMUS-BASED IMMUNOSUPPRESSION

Code: NODAT-BELATAC

Sponsor: Fundació Hospital Universitari Vall d'Hebron - Institut de Recerca (VHIR)

Principal Investigator: José Moreso

Justification of termination of the trial

The main goal of this study was to compare the incidence of glucose metabolism alterations (defined as per the American Diabetic Association) at any time point up to 6 months after kidney transplantation, in a regimen based on Tacrolimus in comparison with that based on Belatacept.

Trial was prematurely ended since it was linked to funding of the new drug by the Spanish National Health System, which was finally not obtained, so it was impossible to complete the assay without extra funding. Only 16 patients were finally recruited, out of the 96 expected. No results were obtained in the assay, as statistics were impossible to obtain without completing the treatment.