

Protocol title:

Treatment of Patients with Post-transplant Lymphoproliferative Disorders (PTLD) with a sequential treatment consisting of Anti-CD20 Antibody (Rituximab) and CHOP + GCSF chemotherapy

Synopsis of Protocol

Project Phase:	II
Indication:	Untreated CD20+ lymphoproliferative disorders following transplantation of organs.
Objectives:	To determine the safety and the efficacy of a sequential therapy consisting of rituximab antibody followed by CHOP chemotherapy in patients with CD20+ Post-transplant lymphoproliferative disorder (PTLD) after organ transplantation.
Study design:	Open label, single arm study.
Planned sample size:	100 patients
Number of centers:	30
Patient selection criteria:	Female or male patients with confirmed lymphoproliferative disorders after organ transplantation (e.g. heart, lung, liver, bone marrow and kidney etc.) with stage I-IV.
Study medication:	Treatment with the anti-CD20 monoclonal antibody rituximab. The antibody will be given at a dosage of 375 mg/m ² i.v. infusion, once a week for 4 infusions. After an interval of 4 weeks 4 cycles of CHOP 21 chemotherapy will be given
Main parameters of efficacy:	Objective response rate.
Main parameters of safety:	Adverse events.
Statistical analysis:	Descriptive statistics.
Duration of the study:	36 months.