

SAMENVATTING TamVen

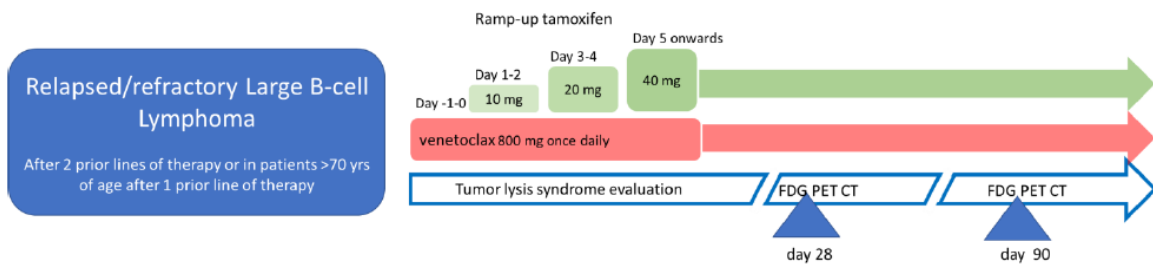
TITEL

An explorative safety and feasibility study of Venetoclax combined with Tamoxifen in patients with relapsed/refractory Diffuse Large B-cell Lymphoma

INDICATIE

Patients with relapsed/refractory DLBCL younger than 70 years after at least 2 lines of conventional chemotherapy. Patients with relapsed/refractory DLBCL older than 70 years after at least 1 line of conventional chemotherapy

SCHEMA



INCLUSIE CRITERIA

- Patients of 18 years and older and under the age of 70 with a diagnosis of Diffuse Large B-cell lymphoma (DLBCL) and High-grade B-cell lymphoma (HGBCL) (according to WHO 2016) and refractory after at least 2 lines of therapy, including an anti-CD20 monoclonal antibody therapy, anthracyclines and chimeric antigen receptor (CAR) T-cell therapy. Patients with relapsed/refractory DLBCL/HGBCL older than 70 years and ineligible for high dose chemotherapy with autologous stem cell transplantation rescue or CAR T-cell therapy, after at least 1 line of conventional chemotherapy.
- Written informed consent.
- No known allergy to Ven or Tam

EXCLUSIE CRITERIA

- Eastern Cooperative Oncology Group (ECOG) performance status >2
- Absolute neutrophil count (ANC) <1,000/ μ L
- Platelet count <50,000/ μ L
- Absolute lymphocyte count <100/ μ L
- Primary and secondary CNS lymphoma
- Active systemic fungal, viral or bacterial infection, unless treated and controlled
- Liver dysfunction as indicated by total bilirubin, AST and/or ALT >5 x institutional ULN, unless directly attributable to patient's tumor or Gilbert disease
- CrCl <30 mL/min calculated according to the modified formula of Cockcroft and Gault or by direct urine collection

- Pregnant or breast-feeding woman
- Woman who is still reproductive
- Active secondary malignancy requiring treatment
- The use of strong CYP3A4 inhibitors or inducers (see Appendix C for specific medication)
- The use of strong CYP2D6 inhibitors or inducers (see Appendix C for specific medication)
- Long-QT-syndrome