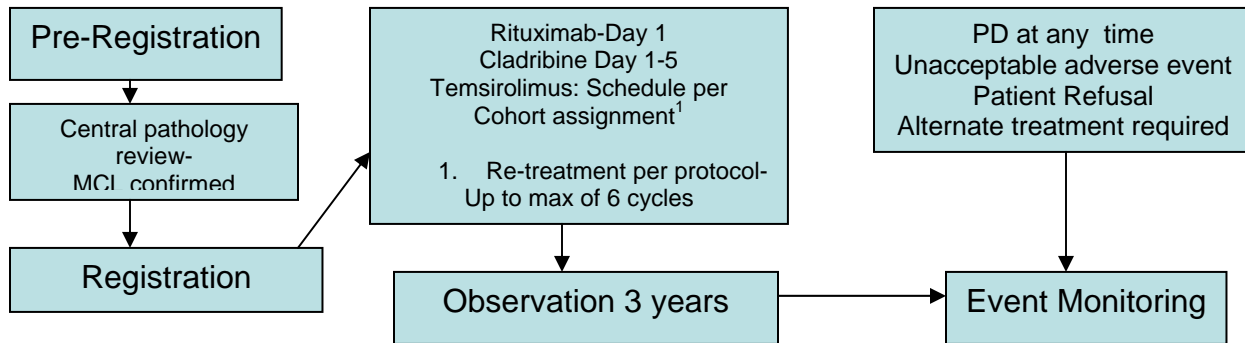


N078D-Phase I/II Trial of Rituximab, Cladribine, and Temozolomide (RCT) in newly Diagnosed Mantle Cell Lymphoma (MCL)

SCHEMA



This is a Phase I/II study utilizing Rituximab, Cladribine, and Temozolomide in patients who are newly diagnosed with Mantle Cell Lymphoma. The Phase I will determine the MTD of Temozolomide that can be given in combination with Rituximab and Cladribine. The Phase II will be a straight Phase II study utilizing the MTD of Temozolomide with Rituximab and Cladribine from the Phase I portion of the study.

Key Eligibility Criteria:

- Histologically confirmed MCL, with NCCTG pre-registration central pathology confirmation.
- Tumor must be cyclin D1 positive by IHC, or have evidence of a t (11;14) translocation by FISH or cytogenetics.
- Measureable or assessable disease²
- ECOG PS of 0,1,2 or 3
- Adequate hematologic values (ANC \geq 1500 and plts \geq 100,000)
- Adequate renal (cr. \leq 2.0 mg/dL) and liver function (tot. bili \leq institutional ULN and SGOT \leq 3x institutional ULN or \leq 5 x institutional ULN if liver involvement).
- Willingness to provide mandatory blood and tissue specimens.

Key Exclusion Criteria:

- Pregnant or nursing women.
- Patient who have had prior treatment for MCL (including radiation)-splenectomy allowed for diagnosis, cytopenia, or splenomegaly.
- Active or uncontrolled infection
- Cardiac conditions as defined in the protocol²
- Known CNS involvement
- Concurrent malignancy \leq 5 years²
- Stem cell transplant planned as part of initial therapy
- Receiving EIAC's or other potent CYP3A4 inducers²

1 Refer protocol for complete criteria

2 Refer to protocol for more complete criteria

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