


Comparison between bendamustine and chlorambucil in combination with rituximab in patients with chronic lymphocytic leukemia ineligible for fludarabine-based therapy

 Fludarabine-ineligible patients with chronic lymphocytic leukemia (CLL)



6 cycles of chemotherapy treatment for 4 weeks



178

Rituximab

375 mg/m² D1, C1
500 mg/m² D2, C2-C6

+

Bendamustine

VS



179

Rituximab

375 mg/m² D1, C1
500 mg/m² D2, C2-C6

+

Chlorambucil

1L patients

90 mg/m² D1 and D2, C1-C6 (n=121)

2L patients

70 mg/m² D1 and D2, C1-C6 (n=57)

10 mg/m² D1-D7, C1-C6 (n=120)

Chlorambucil monotherapy for
additional ≤6 cycles (n=59)

Primary endpoint (1L)

Complete response rate

24% (9/121)

9% (11/120)

P=0.002

Secondary endpoint (1L)

Progression-free survival

39.6 months

29.9 months

Log-rank P=0.003

Overall survival

43.8 months

not reached

Log-rank P=0.939

MRD-negative patients

41% (49/121)

13% (16/120)

Safety

98% (173/178)

97% (173/179)

Rituximab plus bendamustine may be a valuable first-line option for fludarabine-ineligible patients with CLL