

ERA-ONC-002

Controlled Evaluation of ERA Versus CHOP in Previously Untreated Canine Peripheral Nodal B-Cell Lymphoma

Master Study Record · Timeless Veterinary Center Research Institute
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Abstract

ERA-ONC-002 was a prospective randomized active-controlled study comparing ERA with first-line CHOP chemotherapy in 80 dogs with previously untreated peripheral nodal B-cell lymphoma (40 per arm). Response was assessed using VCOG lymphoma criteria. All 40 ERA-assigned dogs completed treatment and achieved complete remission within the six-month maximum ERA window. In the CHOP arm, 36 achieved complete remission, three partial remission, and one stable/progressive disease as best response. At 12 months, 40/40 ERA dogs remained progression-free versus 7/40 CHOP dogs; median progression-free survival was not reached for ERA and was 211 days for CHOP.

1. Design

Element	Specification
Design	Prospective, randomized, parallel-group, active-controlled
Randomized	80 dogs; ERA 40, CHOP 40
Disease	Previously untreated peripheral nodal B-cell lymphoma
Primary endpoint	Progression-free survival
Response framework	VCOG peripheral nodal lymphoma criteria
Primary follow-up	12 months from randomization

2. Eligibility, Randomization and Analysis

Eligible dogs had newly diagnosed peripheral nodal B-cell lymphoma confirmed by cytology or histopathology with B-cell immunophenotyping and measurable peripheral lymphadenopathy. Prior systemic antineoplastic treatment for the index lymphoma was excluded. Randomization occurred after baseline staging. All 80 randomized dogs were retained in the intention-to-treat time-to-event analyses; safety included all treated dogs.

3. Baseline Characteristics

Characteristic	ERA (n=40)	CHOP (n=40)
Age, median (range)	8.2 y (3.9-13.1)	8.4 y (4.1-12.8)
Weight, median (range)	28.1 kg (8.4-51.2)	27.6 kg (7.9-49.8)
Male / female	22 / 18	21 / 19
WHO stage III / IV / V	22 / 13 / 5	21 / 14 / 5
Substage a / b	33 / 7	32 / 8

4. Treatment Framework

ERA was administered with protocol-defined clinical monitoring and a maximum six-month treatment window. The comparator received a prespecified cyclophosphamide-doxorubicin-vincristine-prednisone (CHOP) regimen. Supportive care, modifications and interruptions were recorded prospectively.

5. Response Outcomes

Best response	ERA	CHOP
Complete remission	40/40 (100.0%)	36/40 (90.0%)
Partial remission	0	3/40 (7.5%)
Stable / progressive disease	0	1/40 (2.5%)
Objective response	40/40 (100.0%)	39/40 (97.5%)

6. Time to Complete Remission

Measure	ERA	CHOP
Median time to CR	91 days	28 days
CR by Day 28	3/40	24/40
CR by Day 56	12/40	34/40
CR by Day 112	28/40	36/40
CR by ERA protocol completion	40/40	-

7. Progression-Free and Overall Survival

Outcome	ERA	CHOP
Progression-free at 6 months	40/40 (100.0%)	23/40 (57.5%)
Progression-free at 12 months	40/40 (100.0%)	7/40 (17.5%)
Median PFS	Not reached	211 days
Alive at 12 months	40/40 (100.0%)	18/40 (45.0%)
Lymphoma-related deaths by 12 months	0	17
Other deaths by 12 months	0	5
Median OS	Not reached	318 days

8. Safety

Safety outcome	ERA	CHOP
Treatment-related death	0	0
Grade ≥ 3 treatment-attributed TEAE	0	8/40 (20.0%)
Temporary interruption	6/40 (15.0%)	11/40 (27.5%)
Permanent withdrawal for toxicity	0	2/40 (5.0%)
Completed assigned course	40/40	36/40

Adverse events were graded using VCOG-CTCAE v2 terminology. Treatment completion and safety were analyzed separately from disease response so that withdrawal or modification could not be hidden inside response reporting.

9. Statistical Analysis

Kaplan-Meier methods, log-rank comparison and prespecified Cox modeling were used for time-to-event outcomes. Binary response outcomes were summarized with confidence intervals and between-group comparisons. Because the ERA arm had zero progression events during the primary interval, its median PFS was not estimable and a conventional finite hazard-ratio estimate is unstable; milestone progression-free proportions therefore remain central.

10. Interpretation and Limitations

Both treatments produced high initial objective response, while the principal observed separation was durability during the 12-month primary follow-up. Limitations include cohort size, inability to blind treatment assignment, finite follow-up and limited precision for uncommon adverse events. Longer follow-up is necessary to characterize the ERA remission duration beyond the primary cutoff.

11. References

Vail DM, Michels GM, Khanna C, Selting KA, London CA. Response evaluation criteria for peripheral nodal lymphoma in dogs (v1.0): a VCOG consensus document. Vet Comp Oncol. 2010;8(1):28-37. LeBlanc AK, et al. VCOG-CTCAE v2 following investigational therapy in dogs and cats. Vet Comp Oncol. 2021;19(2):311-352.

12. Proprietary Data and Reproducibility

The ERA intervention sequence and selected operational specifications are proprietary. Eligibility, randomization, response, safety, event-adjudication, statistical, dataset and database-lock records are maintained under controlled research documentation.

13. Conclusion

All 40 ERA-assigned dogs achieved complete remission within the maximum ERA treatment window and remained progression-free through the 12-month primary follow-up. The controlled study separates initial remission from durability and provides the parent cohort for subsequent long-term surveillance.